COMPUTER DETECTION OF DIABETIC RETINOPATHY COMPARED TO CLINICAL EXAMINATION [IDX]

Oracle Clinical™ Remote Data Capture (RDC) Onsite 4.6 User's Manual

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Prepared by:
Clinical Research Computing Unit (CRCU)
Center for Clinical Epidemiology and Biostatics (CCEB)
University of Pennsylvania School of Medicine
3535 Market Street, Suite 560
Philadelphia, PA 19104-3309

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System Requirements

Personal Computer (PC) Requirements

In order to operate the ***Oracle Clinical Remote Data Capture (RDC) Onsite*** application, your computer must meet the following requirements:

- Windows XP Home or Professional 2K or Windows 7.
- Internet Explorer (IE) 7 and 8 (IE 9 certification pending)
- Adobe Acrobat Reader (or Professional) 7 or above.

  If Adobe is not installed, it can be downloaded from the Adobe website – http://www.adobe.com. Follow the installation instructions provided on the Adobe website.
- If the internet browser's popup blocker is enabled, make sure to allow popups from the following websites: http://rt4.cceb.med.upenn.edu and http://rt9.cceb.upenn.edu.
- Disable ***Yahoo Search, Google Toolbar, AOL Toolbar, Windows Messenger*** add-ons.

  To disable them in IE 6, the add-on needs to be removed using the Control Panel's "Add or Remove Programs" tool.

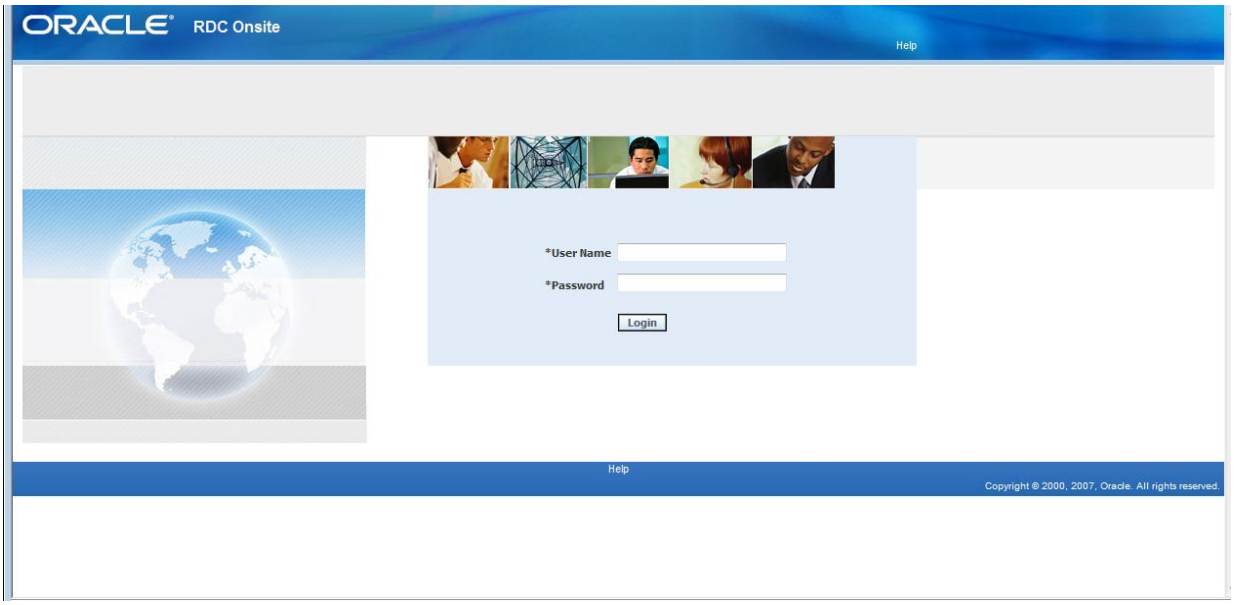
  To disable then for IE 7 or above, go to the Tools menu and select Manage Add-ons; click on the add-on and check 'Disable'. Repeat for each add-on found. You need to restart IE for the changes to take effect.

Logging-In

Data Management System (DMS)

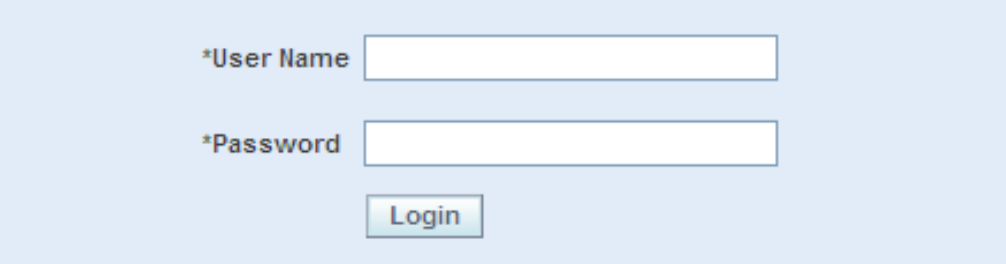
1. Access the Login Page of RDC Onsite by entering the following URL – https://rt9.cceb.med.upenn.edu/olsa/oc/rdcLogin.do - for RDC Onsite 4.6 into an Internet Explorer web-browser.
2. Enter user name and password
3. Click ***Login*** to launch the application.

   Tip: Users can also bookmark the above address in the Internet Favorites of their browser.



This will allow access to the IDX training database initially, and after certification, you will be given access to the live study database. A ***News Item*** (next section) will describe which database is being accessed.

4. In the Log-in box enter the Username and Password provided by the CRCU Database Administrator:



Username: _____

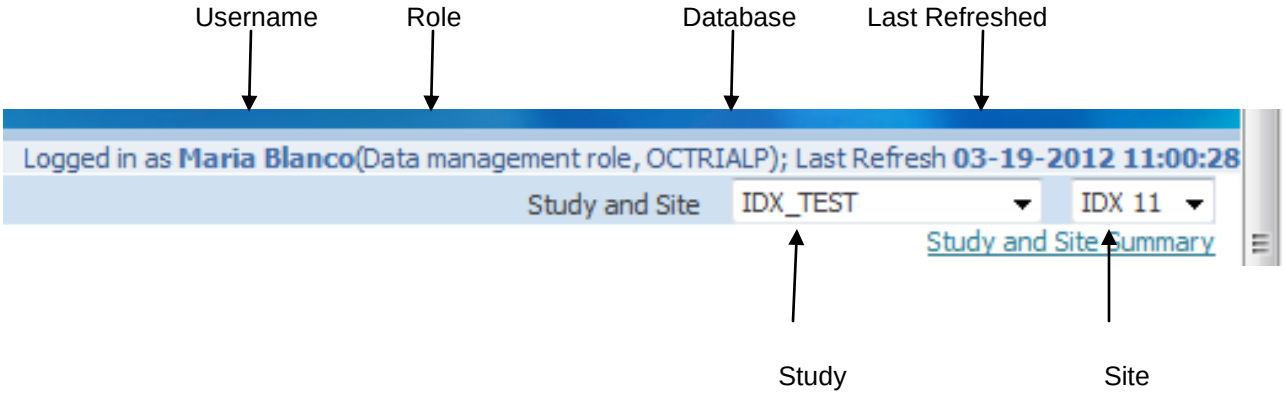
Password: _____

5. Click "Login"

Tip: This Username and Password will be used for all *applications*

It is important that you keep your login information confidential. This information acts as an electronic signature, and attaches your name to any changes, updates, additions, or modifications within the Oracle Clinical system and can be tracked through the Audit Trail.

RDC Onsite displays the session information in the upper right hand corner of the Home Page, under the global links. Session information will be visible on every page throughout the RDC Onsite Application:

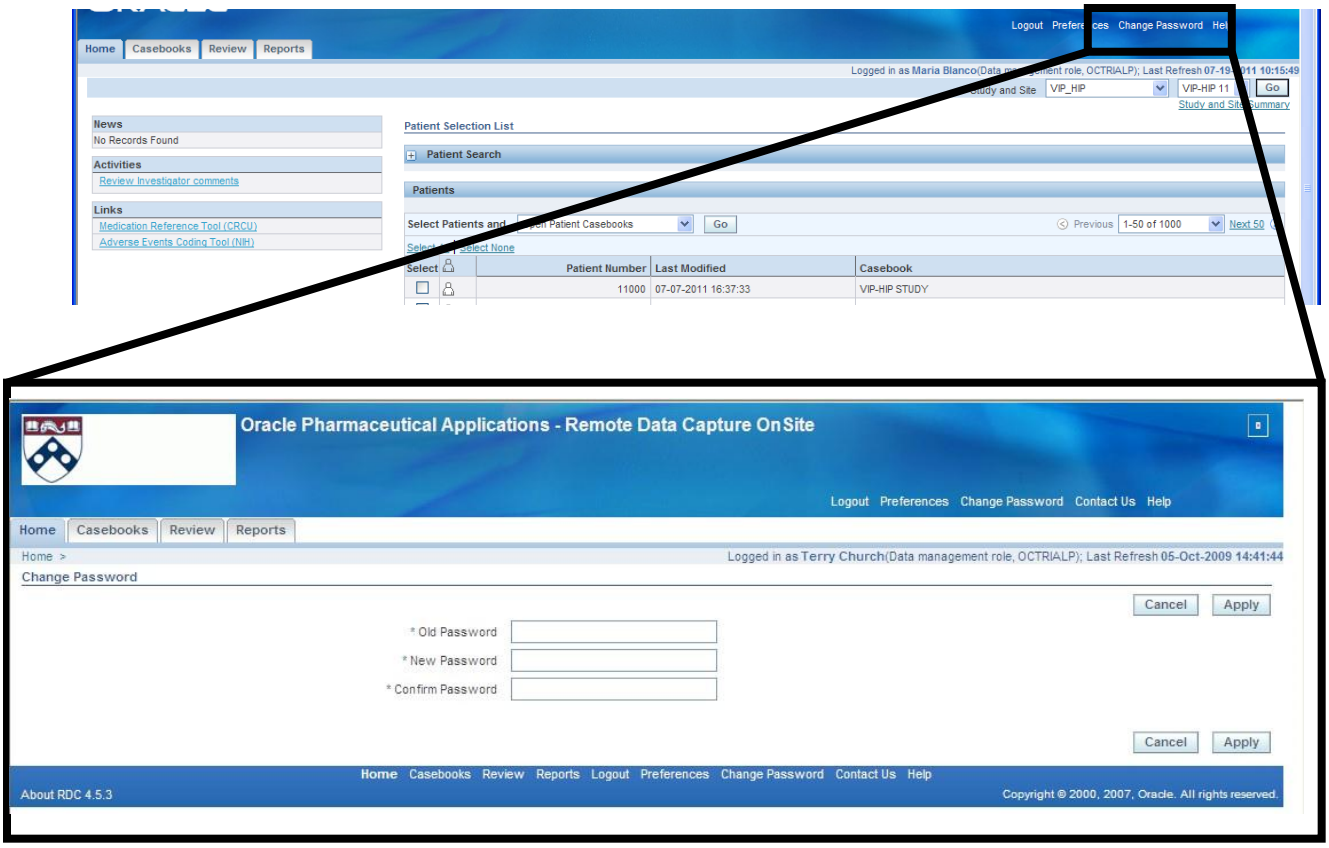


Username:	Your first and last name.
Role:	Role corresponds to your username. Different roles have different levels of access and privileges within the RDC Onsite application.
Database:	Displays the name of the database to which you are currently logged into.
Last Refreshed:	Displays the date and time the view was last refreshed in response to any action from you, such as entering and saving data on a participant.
Study:	The name of the Study you are currently logged into will appear here. The dropdown list allows you to select from the studies you have access to, such as IDX.
Site:	The name of the Site currently logged into. Ability to select sites from the dropdown menu is dependent upon your account's access permissions.

Password Management

Steps to change Passwords, after logging into RDC Onsite:

1. Click ***Change Password*** in the upper right-hand corner of the header of the RDC Onsite 4.6 Home Page.
2. Enter the old password in the ***Old Password*** field.
3. Enter the new password in the ***New Password*** field.
4. Re-enter the new password in the ***Confirm Password*** field.
5. Click ***Apply*** to process the change.

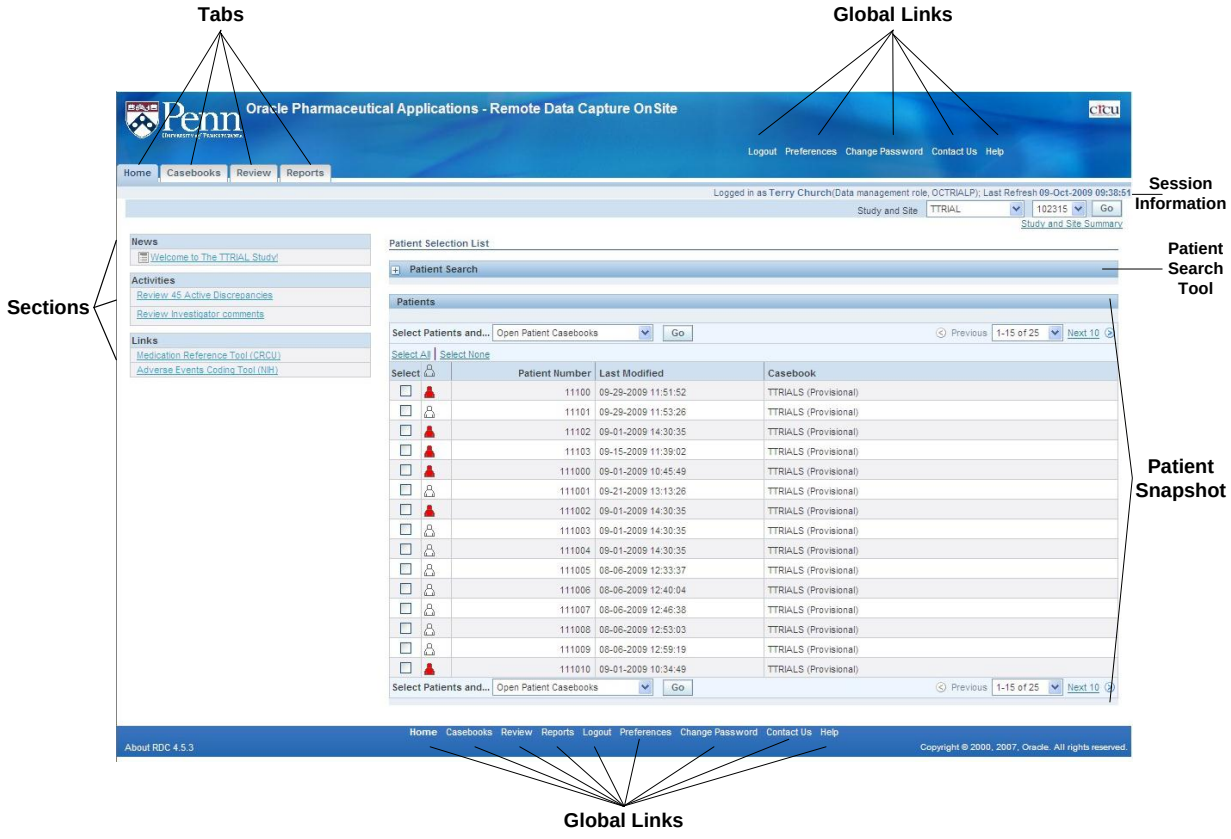


DMS Navigation and General Overview

Home Page in RDC Onsite:

Below is a snapshot of the RDC Onsite Home Page, the following features will be described in more detail throughout this section:

- Tabs
- Sections
- Global Links
- Patient Snapshot
- Patient Search Tool
- Session Information



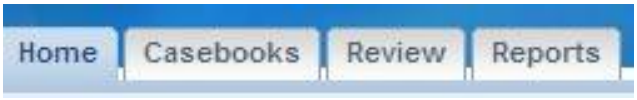
RDC Onsite organizes and displays information in pages, oriented towards user tasks. There are two main types of pages that make up RDC Onsite:

Surround Pages: The ***Surround pages*** provide a way for you to review and interact with data. Examples of the Surround pages include: Home Page, the Casebook Page, the Review Page, and the Reports Page. All of which are accessible via the Tabs.

Data Entry Window (DEW):
The ***Data Entry Window (DEW)*** displays a Case Report Form (CRF) that you can select and open from the Casebooks and Review Surround Pages.

Home Page in Review:

Tabs act as navigational tools presented in the upper left corner (like file tabs) and are also incorporated into the global links at the bottom of each page throughout the RDC Onsite application.



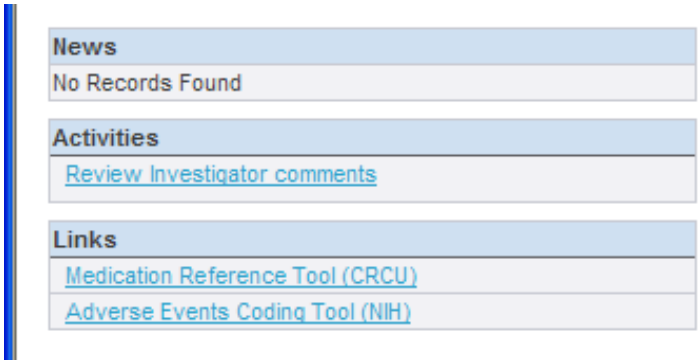
Home: Home Page appears when logged into RDC Onsite and acts as the activity page – providing News Items, Actionable Items, Snapshots, and Search functionalities.

Casebooks: Casebooks Tab allows access to the *only* page in RDC Onsite where data entry into a CRF can be initiated.

Review: Review Tab access pages from which you can review general information about CRFs, discrepancies, and investigator comments (these dialog boxes are available as sub-tabs on the Review Page).

Reports: Reports tab accesses the Reports Page where users with the appropriate role can generate Patient Data Reports – NOTE: This Feature is NOT available for all users.

Sections provide information and a snapshot of actionable items.



News: Details pertinent study, site, or database information published by the Data Coordinating Center (DCC) at the CRCU (Clinical Research Computing Unit). Examples of potential News items: RDC Onsite system downtime for maintenance, Training or Production Data Management System (DMS) being accessed, specific site information, and upcoming data related milestones, etc.

Activities: Provides customized tasks based on your role. The tasks are displayed as hyperlinks. Click the link Review Investigator Comments or Review Discrepancies to access the ***Review Page*** and activate the ***Review Discrepancies*** page to view only those that require your attention.

Links: Reference links that are external to the RDC Onsite system. These links can be private (password protected) or public sites.

Global Links are located across the bottom (full list of links) and in the right corner (subset list of links) of each application page within RDC Onsite.

(Full List of Links – Bottom of the Screen)

Home: Access to the Home Page within RDC Onsite.

Casebooks: Access to the Casebooks Page and allow data entry within RDC Onsite.

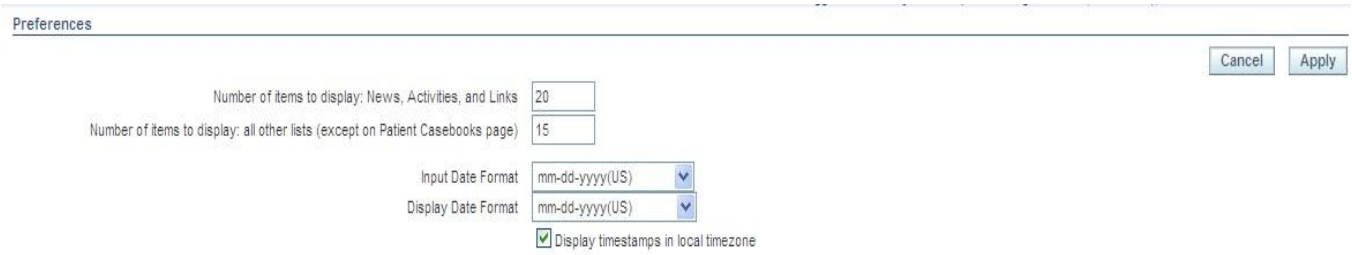
Review: Access to the Review Page within RDC Onsite.

Reports: Access to the Reports Page within RDC Onsite.

Logout: Logout of RDC Onsite. The Home Page Session view will display the site and study last visited.

IMPORTANT: For Security, use the ***LOGOUT*** *t*o securely end a given session. Do not close or "X" out of a window and assume you have been successfully logged out of the application.

Preferences: Change the way RDC Onsite displays data.



Number of News items, Activities, and Links to display:
Specify the maximum number of items to be displayed in the News, Activities, and Links section of the Home Page. If the number of items exceeds the maximum display limit specified here, RDC Onsite will add **NEXT** and **Previous** links within the section boxes.

Number of items to display, all other lists (except on Patient Casebooks page):
Specify the maximum number of patients, CRFs, discrepancies, and investigator comments to be displayed at a time on the Home Page and Review Page within RDC Onsite.

Input Date Format: Change the way the date is recorded during data entry. The formats are: US (mm-dd-yyyy), European (dd-mm-yyyy), and Swedish (yyyy-mm-dd). The ***STANDARD OPTION*** is US format (mm-dd-yyyy).

Display date format: Change the way the date gets displayed throughout the RDC Onsite application. The formats are the same as described above.

Display time stamps in local timezone:
Display timestamps in the local time zone. This will only affect audit trail information displayed, such as Last Modified, when looking at discrepancy information in the review tab.

APPLY to save any changes entered, ***CANCEL*** to return to the previous page.

Change Password: will allow the user to change their password, as described in the Logging-In section.

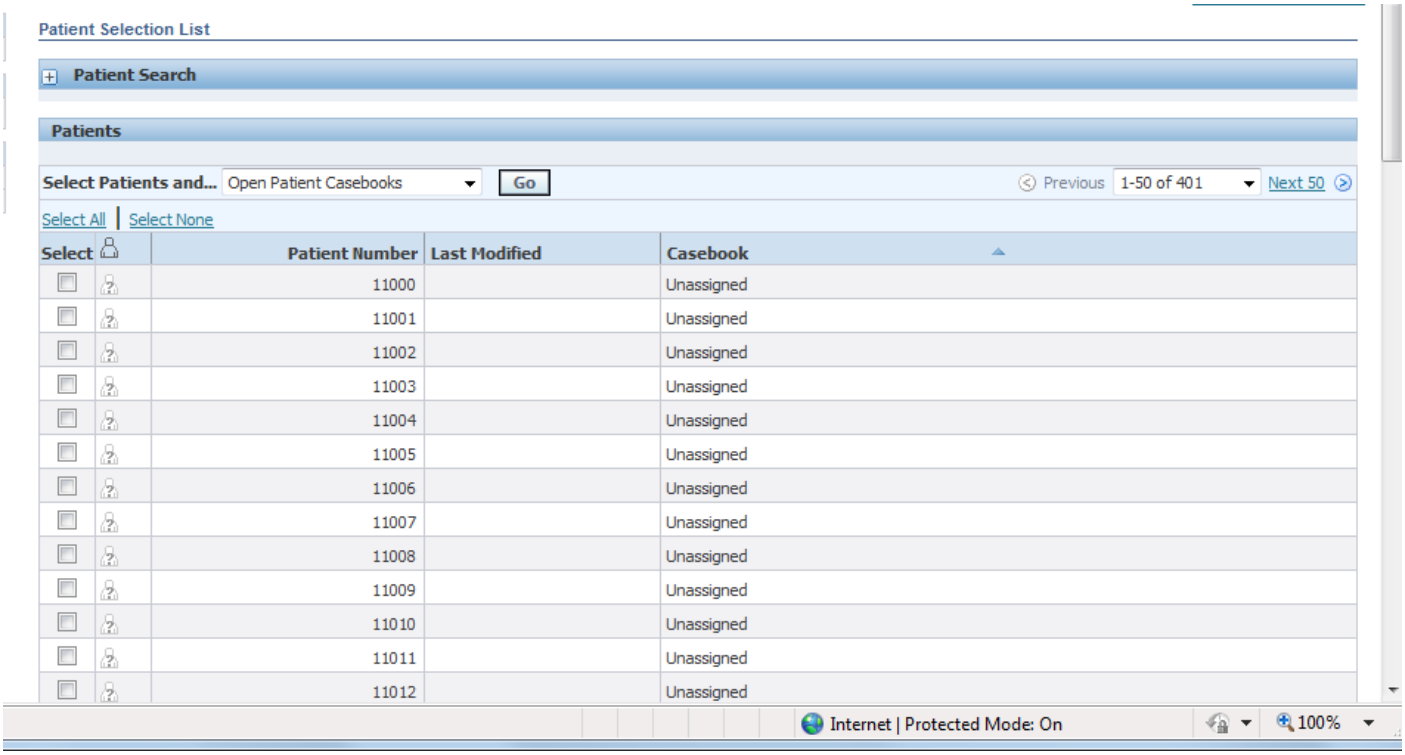
Contact Us: will allow the user to email technical questions or issues directly to the Help Desk: crcuhelp@mail.med.upenn.edu.

Help: will allow the user to open a web based help dictionary on a variety of RDC Onsite related topics.

Participant Selection

Patient Snapshot or Patient Selection List is located on the Home Page and lists a snapshot of patients for the site.

The Patient Snapshot consists of two components – ***Patient Search and Patients:***



Patient Search: Displays a subset of patients.

Range: Search a range of patient numbers in terms of FROM and TO. Click on the magnifying glass icon to select values from the patient identifier list and also to define a range. Blank patient Range fields indicate that all patients should be displayed. Only entering one number in either the FROM or TO will return only that patient number.

Assigned Book: The name of the patient casebook (IDX TEST etc).

Show: View three possible "sets" or groups of patients:

All – all patients are shown. This is the Default view.

Patients with data entered – select this view to review data already entered. On the Home Page and Casebook Page selecting this option will eliminate patient rows from view for those patients who have no saved data.

Patients with no data entered – select this view when initiating data entry for new patients. This view will only show patients who have no data entered and are available for data entry.

Discrepancy Status:

View patients with discrepancies. From the Home Page view the results appear as patient-

level discrepancies (patients with discrepancies); other pages within the RDC Onsite application display results CRF-level discrepancies. ***The discrepancy statuses are:***

All – all patients regardless of their discrepancy status are displayed. This is the default value.

Active – display only patients with active discrepancies. These discrepancies are based on logic checks, range checks, and other study defined criteria per CRF.

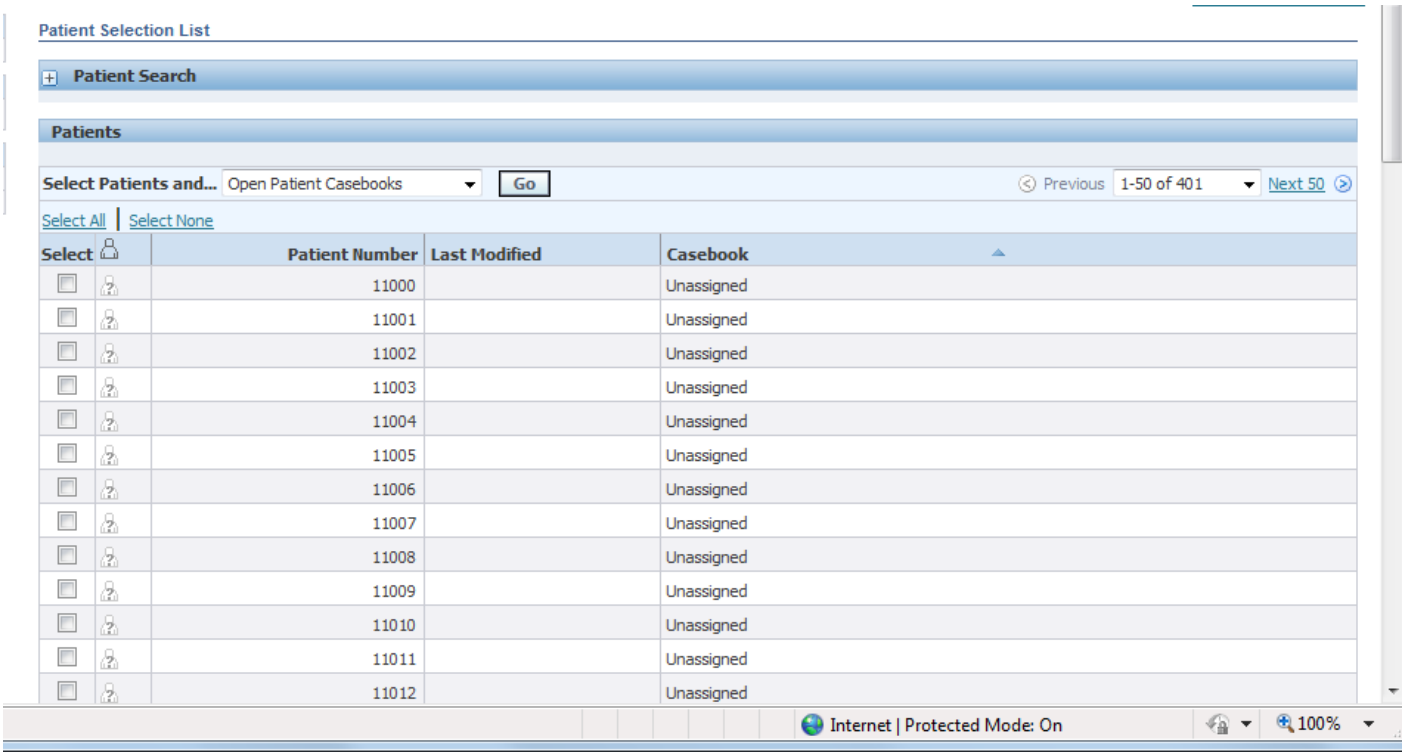
Other – display only patients with other discrepancies. These are system based discrepancies (AE Coding in Progress, AE Event Not Found) or are manually created to obtain further information about a given variable.

Open (Active & Other) – display open discrepancies that are active and other.

Clean (None or Closed) – retrieve patients with no open (active or other) discrepancies.

Patients: Provides brief information about each patient depending upon the search criteria selected.

The description below refers to patients for a site that have had no search criteria entered.



Select: Select patient by checking the box in the first column.
In "Select Patients and…", select an action to execute on the patients from the dropdown menu:

Open Patient Casebooks – open the casebooks for the selected patients.

Review Discrepancies – review open discrepancies for the selected patients.

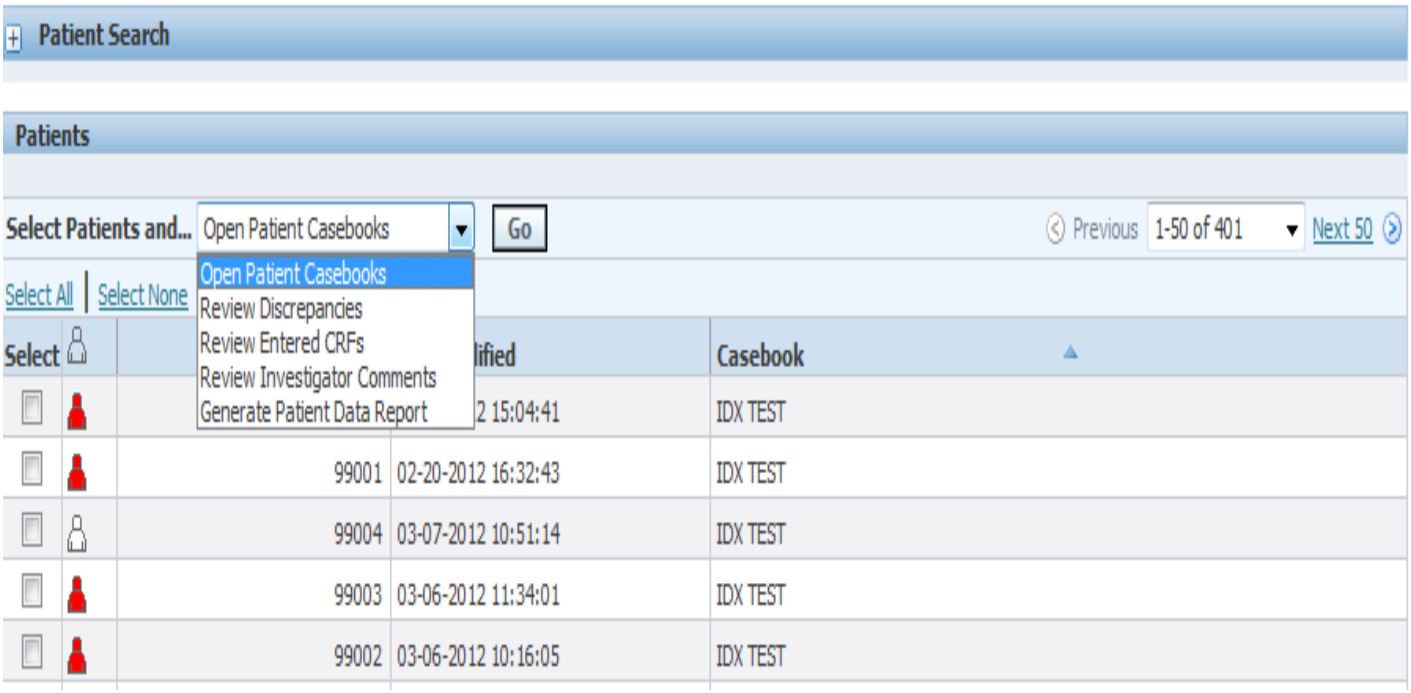
Review Entered CRFs – review entered CRFs for the selected patients.

Review Investigator Comments – review investigator comments for the selected patients.

Generate Patient Data Report – generate general reports on participant data. This feature is not being used for IDX.

Generate Blank Casebook Report – generate blank CRF casebooks per patient. This feature is not being used for IDX.

Review MedDRA Dictionary / AE – review the coded Adverse Event information for the selected patients. This feature is not being used for IDX.



Patient Icons: The patient icon is represented by an anthropomorphic (human looking) figure. The color of the icon signifies the discrepancy status or entry status of a given patient.
See table below:

Icon	Color	Description
	White	Patient data contains no *open* discrepancies.
	Gray with a question mark	No data has been entered for this patient number. The patient number is available to be used for a new patient.
	Red	Patient data includes discrepancies requiring your attention. These are referred to as *active* discrepancies.
	Yellow	Patient data does not include active discrepancies, but includes discrepancies requiring another user's attention. These are referred to as *other* discrepancies.

Patient Number: The patient number or patient identification number (PID) is an assigned unique number for each patient, unique to a given site.

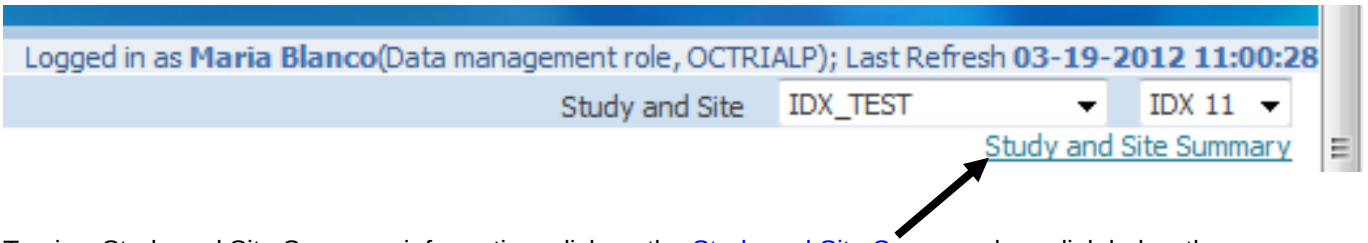
Last Modified: The value in this field repress the date and time of the last modification to the patient's entered data. A modification can represent any of the following actions: data updates, discrepancy resolution, or initial entry of a CRF.

Casebook Name: The casebook name is the name of the casebook (or CRF packet) to which a given PID has been assigned. In the case above, all the patients have been entered into IDXS (Provisional).

Provisional – casebook is currently being developed, enhancements are being made, or testing is being performed. Data entered into a provisional casebook is committed into a study database, but can be removed prior to activation.

Active – casebook is currently active or live. Data entered into an active casebook will be committed to the study database, any subsequent changes to data will be tracked via the audit trail.

Site and Study Summary is shown below the Session information on the Home Page:

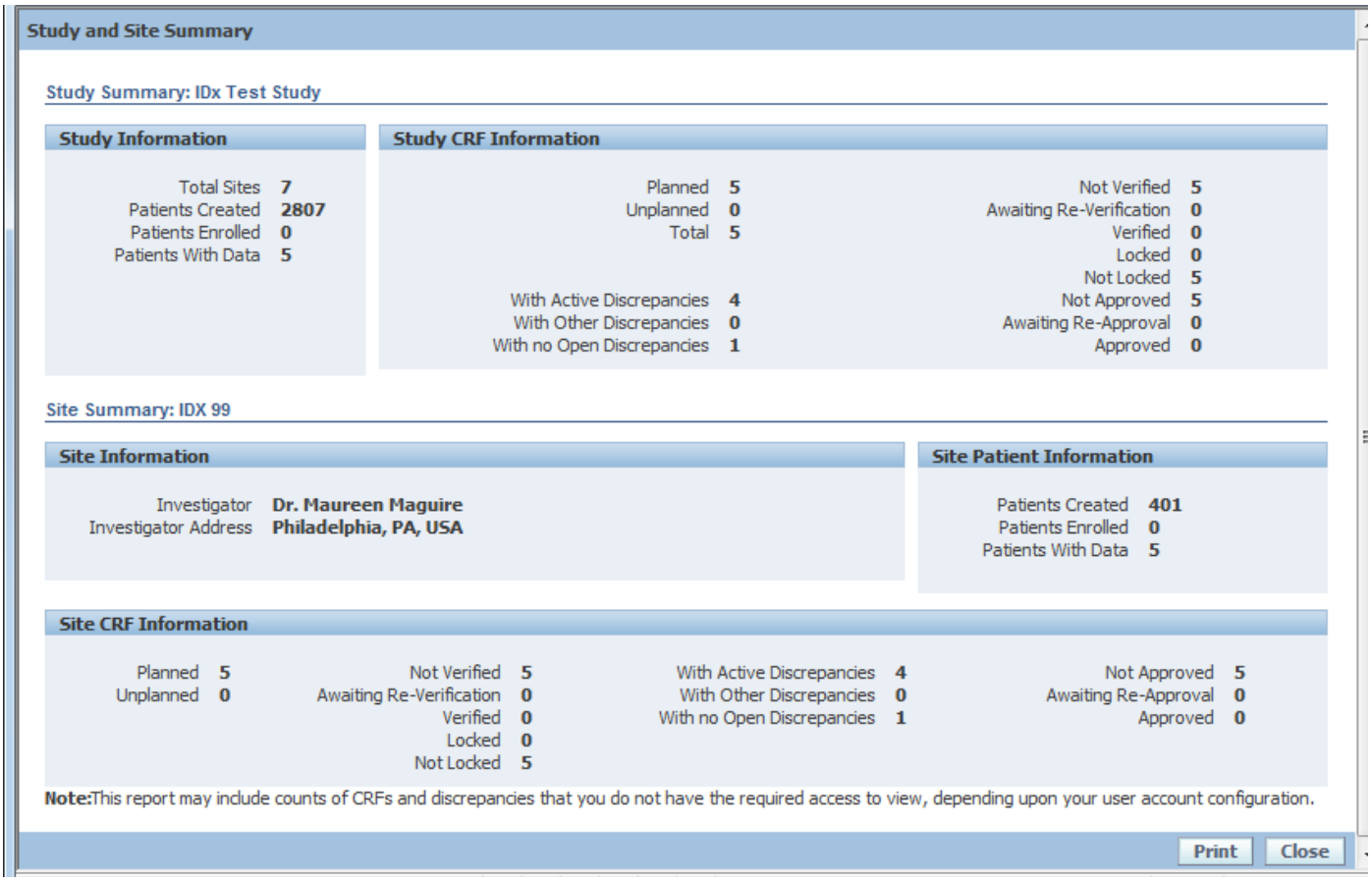

Logged in as Maria Blanco(Data management role, OCTRIALP); Last Refresh 03-19-2012 11:00:28
Study and Site
IDX_TEST
IDX 11
Study and Site Summary

To view Study and Site Summary information, click on the Study and Site Summary hyperlink below the Session information from any of the ***Surround Pages***.

Study and Site Summary information will give a snapshot of data related to:

Study Summary: provides number of sites, number of patients with data, number of CRFs, and number of discrepancies.

Site Summary: provides the name of the Investigator, address of the Investigator, patient summary information, number of CRFs with discrepancies, and number of discrepancy free CRFs.



General terminology from the display above:

Patients Created: indicates the number of patient numbers that have been pre-programmed for the study and for the site.

Patients with Data: represents the number of created patients that have at least one CRF entered and saved in the system.

Planned CRFs: the number of CRFs that have been allotted or planned per visit per patient.

Unplanned CRFs: represents the number of CRFs that were entered as unplanned visits per the existing study matrix ("Unscheduled Blood Draw", "Patient Death") or CRFs that needed additional pages inserted ("Adverse Events", "Concomitant Medications").

With Active Discrepancies: represents the number of CRFs that have open discrepancies.

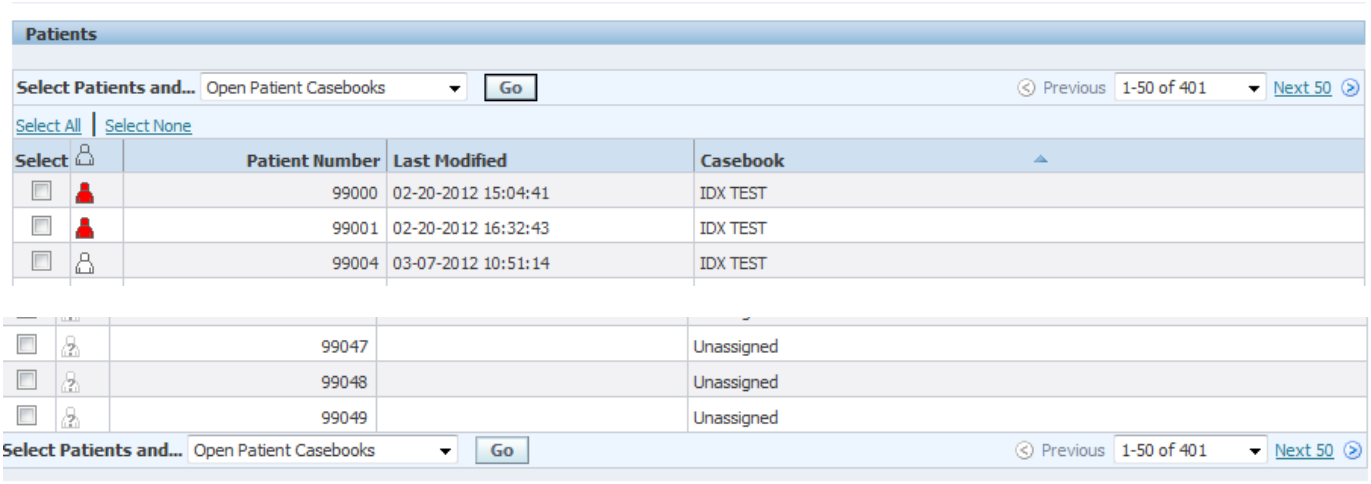
> ***TIP*** – CRF level discrepancies only count forms with errors, this summary report does not represent question level discrepancies within the CRF. *Example*: if a CRF has 5 open discrepancies on the individual questions within the CRF, the statistic will be displayed in this summary view as 1 CRF with discrepancies.

With Other Discrepancies:
represents the number of CRFs that have open discrepancies related to AE coding errors, or queries initiated by the DCC.

With no Open Discrepancies:
represents the number of CRFs without any currently open discrepancies.

Navigational Aids

Navigational Aids in the ***Surround Pages***:



If a list of items is longer than what can be displayed on the page or in a given box, RDC Onsite will present you with navigational aids to help you view any additional data.

To navigate the Surround Pages, use:

Arrows: click the **<** or **>** symbols at the top or bottom portion of a given section to see the previous (**<**) or next (**>**) set of entries.

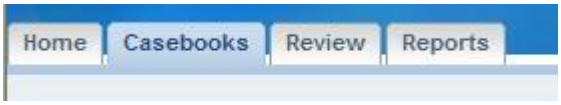
Hyperlink Text: click Previous or Next at the top or bottom portion of a given section to see the previous or next specified number of entries (Next 10 in the example above).

Drop Down List: click the downward arrow next to the drop down box to select a different set of items.

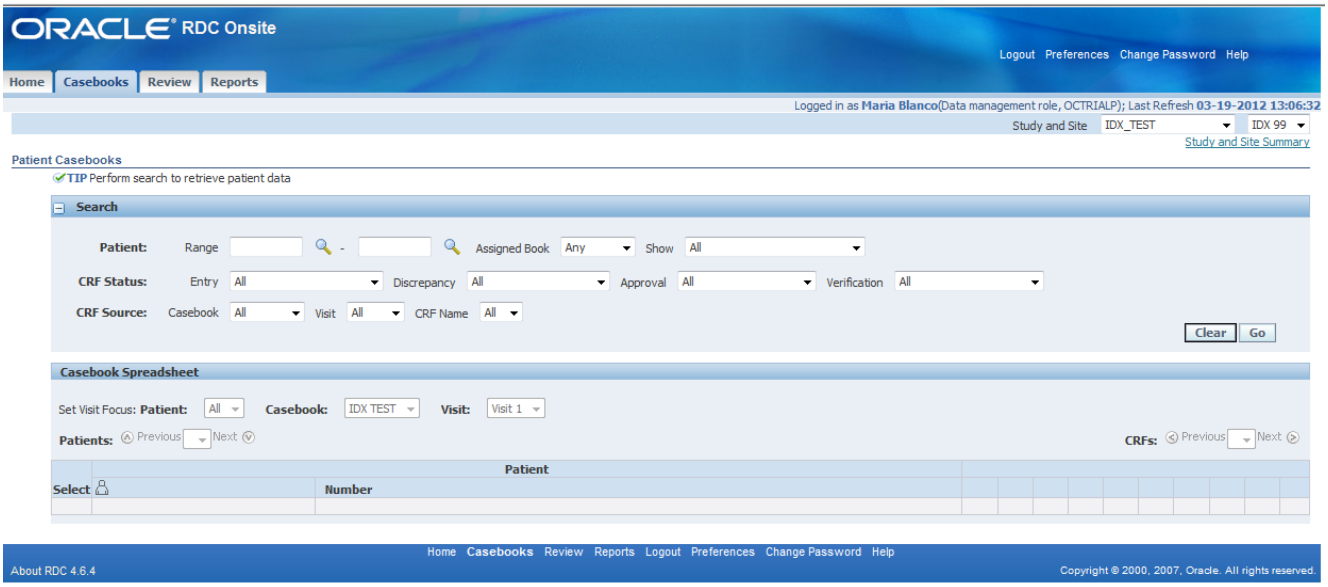
General Data Entry Instructions

Data Entry within RDC Onsite is performed from the Casebook Page. It is the only page in the RDC Onsite application where you can initiate data entry for a CRF.

Casebook Page Data Entry



1. Click on the ***Casebooks*** tab to open the study Patient Casebooks Search and Casebook Spreadsheet display view:


ORACLE RDC Onsite
Logout Preferences Change Password Help
Home Casebooks Review Reports
Logged in as Maria Blanco(Data management role, OCTRIALP); Last Refresh 03-19-2012 13:06:32
Study and Site IDX_TEST IDX 99
Study and Site Summary
Patient Casebooks
TIP Perform search to retrieve patient data
Search
Patient: Range Assigned Book Any Show All
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go
Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: IDX TEST Visit: Visit 1
Patients: Previous Next
CRFs: Previous Next
Patient
Select Number
Home Casebooks Review Reports Logout Preferences Change Password Help
About RDC 4.6.4
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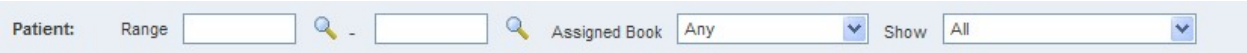
2. To view patients data in the ***Casebook Spreadsheet***, either enter ***search*** parameters or click on "***Go***" in the ***Search*** section of the Casebook Page.

Search
Patient: Range Assigned Book Any Show All
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go

The features of this Search section are similar to the Search section on the Home Page.



The Search options of the ***Patient*** row:

Range: Search a range of patient numbers in terms of FROM and TO.
Click the magnifying glass icon to select values from the patient identifier list and also to define a range. Blank patient Range fields indicate that all patients should be displayed. Only entering one number in either the FROM or TO will return only that patient number.

Assigned Book: The name of the patient casebook (IDX study etc).

Show: View three possible "sets" or groups of patients:

All – all patients are shown. This is the Default view.

Patients with data entered – select this view to review data already entered. On the Home Page and Casebook Page selecting this option will eliminate patient rows from view for those patients who have no saved data.

Patients with no data entered – select this view when initiating data entry for new patients. This view will only show patients who have no data entered and are available for data entry.

The search options of the ***CRF Status*** row:

Entry Status: Select the entry status of CRFs for the study. Each of these entry statuses have a corresponding ICON that is displayed in the Casebook Spreadsheet:

Icon	CRF Label	Description
	Placeholder	No information has been entered.
	Created	The CRF contains required header field information but no response data has been entered.
	Blank	The CRF is marked as blank.
	Entry Complete	All required CRF header and Section header information is complete and at least one question area response field is completed.
	Pass 2 Started	The second pass of data entry has started.This record originates from an Oracle Clinical operation, but your sponsor might create an activity that displays records with this status.
	Pass 2 Complete	The second pass of data entry is completed. This record originates from an Oracle Clinical operation, but your sponsor might create an activity that displays records with this status.
	Batch loaded	The CRF's data was batch loaded. This is a sponsor's operation.

TIP: IDX uses single data entry, and therefore the following ***ICONS*** will not be displayed / used –

- Pass 2 Started
- Pass 2 Complete

Discrepancy Status: View CRFs with discrepancies.
From the Casebook Page view the results appear as CRF-level discrepancies.
The discrepancy status ICONS are:

Icon	CRF Label	Description
	No Discrepancies	There are no Other or Active discrepancies associated with the CRF. (Note that there may be closed discrepancies associated with the CRF.)
	Active	There is at least one Active discrepancy in the CRF, to be addressed by you.
	Other	There is at least one discrepancy that must be addressed by a user in a role other than yours.

Approval Status: View CRF Approval Status for those CRFs that require Principal Investigator (PI) approval of some aspect of data collected on a given CRF or set of CRFs.
The Approval ICONS are:

Icon	Label	Description
	None	The CRF has not been approved.
	Approved	The CRF has been approved.
	Re-approval Required	At least one data point in the approved CRF has been modified since approval. The CRF must be re-approved.

TIP: IDX does not currently have any study specified elements that require electronic approval and this feature of the Search section will not return any associated data. Keep Approval Status set to the default of **ALL** or use **NONE** when searching CRF Status.

Verification Status: View CRF Verification Status for those CRFs that require Principal Investigator (PI) or Study Monitor verification of some aspect of data collected a given CRF or set of CRFs.

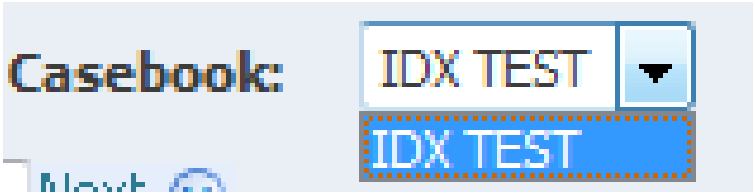
The Verification Status ICONS are:

Icon	Label	Description
	None	The CRF has not been verified.
	Verified	The CRF has been verified.
	Re-verification Required	At least one data point in the verified CRF has been modified since verification. The CRF must be re-verified.

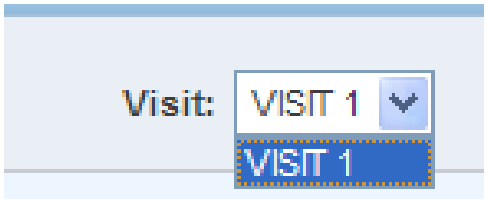
TIP: IDX does not currently have any study specified elements that require additional verification and this feature of the Search section will not return any associated data. Keep Verification Status set to the default of **ALL** or use **NONE** when searching CRF Status.

The Search options for the ***CRF Source*** row:

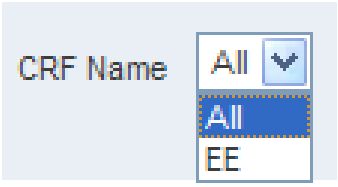
Casebook: will allow users to specify ALL or the study to which they are currently logged in to. From the above, users can select:



Visit: will allow users to select a specific visit name that will display CRF data in the Casebook Spreadsheet. See below for an example, users can select:



CRF Name: will allow users to select a given CRF. CRF Names can be found in the lower right-hand corner of the paper CRFs used for data collection. Below is an example of the CRF choices:

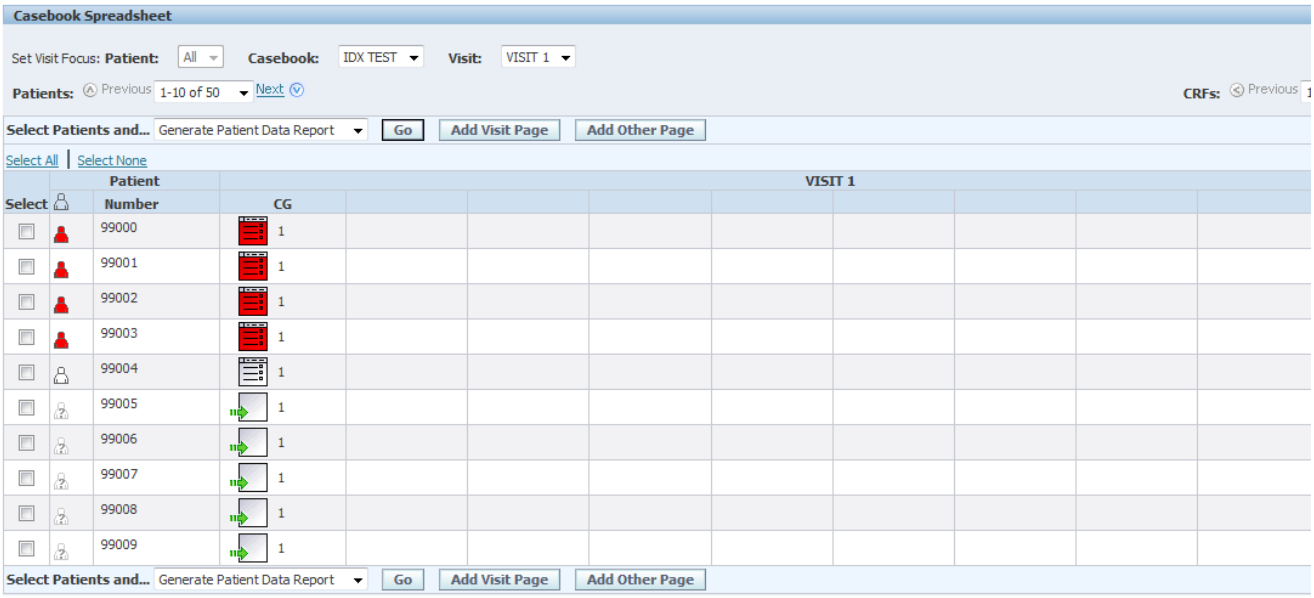


TIP: The IDX study only has one Case Report Form (CRF).

Search
Patient: Range Assigned Book Any Show All
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go

In the above example, the Casebook Search is set to default.

1. Click "Go" to run the patient search with the default parameters. All patient CRFs will be returned (example below).



The above view shows:

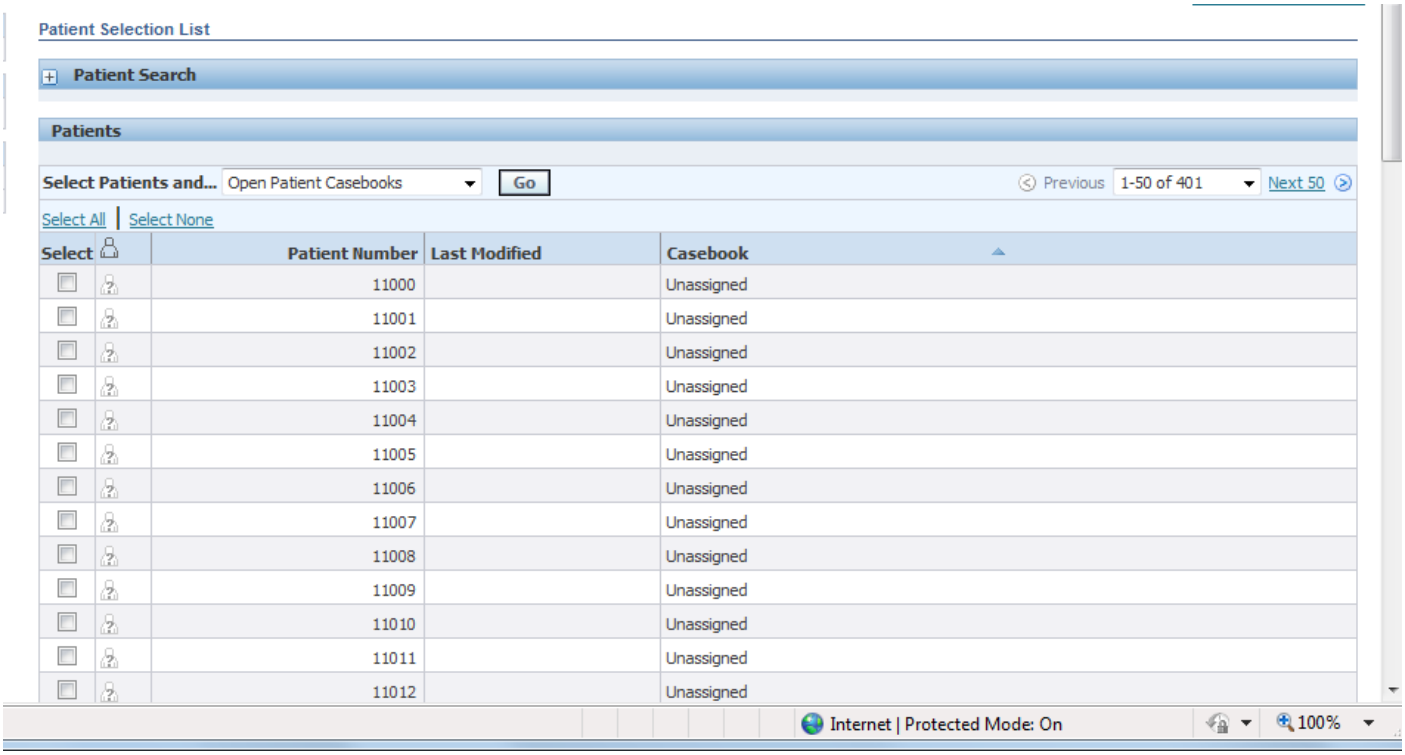
Discrepancies: There are 4 CRF ICONs displayed in the list above. CRF level information is displayed in the Casebook Spreadsheet, which means the red CRF ICON could represent a single discrepancy or multiple discrepancies. For Patient level information, detailing how many open discrepancies per CRF, users would need to Search via the Review Tab. More information can be found in the Discrepancy Management Section of this manual.

Entered: There is one CRF ICON displayed in the list above. Users could enter these CRFs if updates or additions to the previously saved data need to be performed.

Placeholder: There are five CRF ICONs displayed in the list above for five available patient identification numbers. There has been no data entered or saved for these seven CRFs.

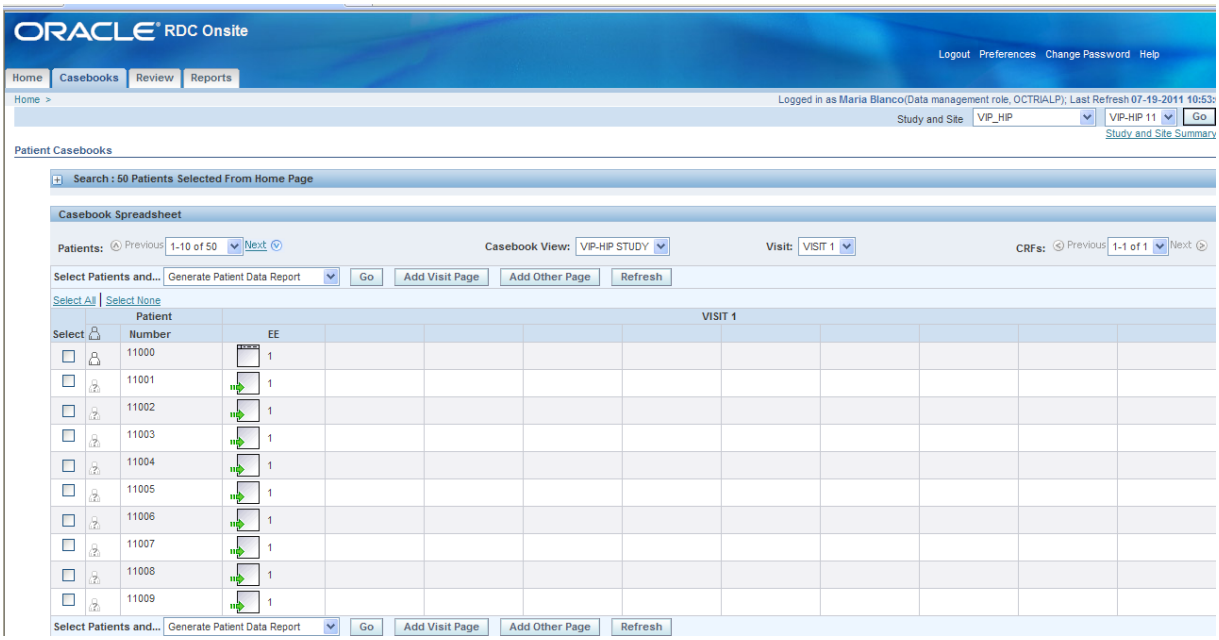
Home Page Selection and Casebook data entry

From the Home Page, you can select a set of patients from the ***Patient Snapshot*** or ***Patient Selection List*** section:

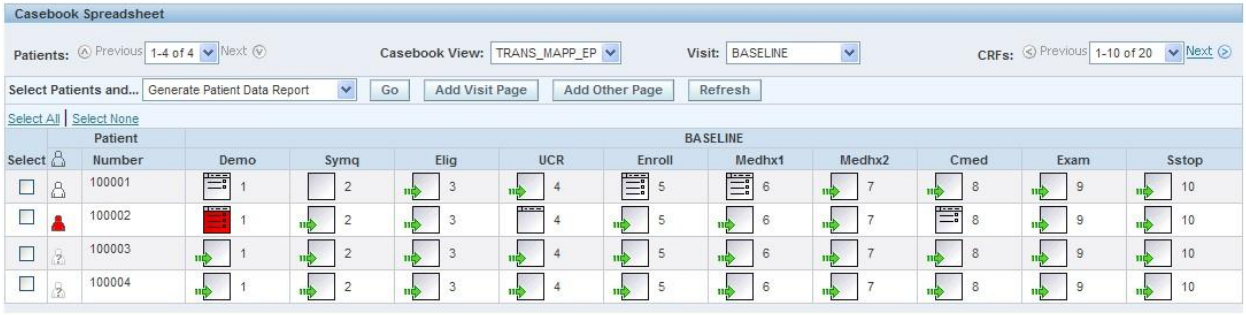


1. ***Select*** the set of patients you'd like to perform data entry for – these can be either patients with current data (continuing data entry) or patients with no data entered (new patient data entry).
2. From the ***Drop Down box*** choose the "Open Patient Casebooks" option.

3. ***Click*** on the "***Go***" button to be taken to the Casebook spreadsheet for the selected patients.



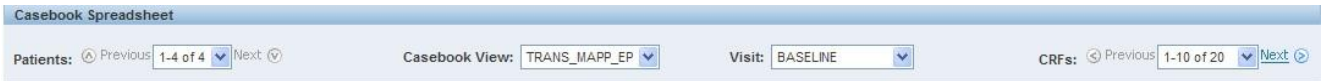
Casebook Spreadsheet overview:



- Casebook Spreadsheets displays patients in rows and the expected, study-related CRFs in columns.
- You can navigate across patients (up and down) and across visit specific CRFs (left to right).

Casebook Spreadsheet controls:

To assist in navigating in the Casebook Spreadsheet, you can make use of the controls located in the top section.



The controls, from left to right, are:

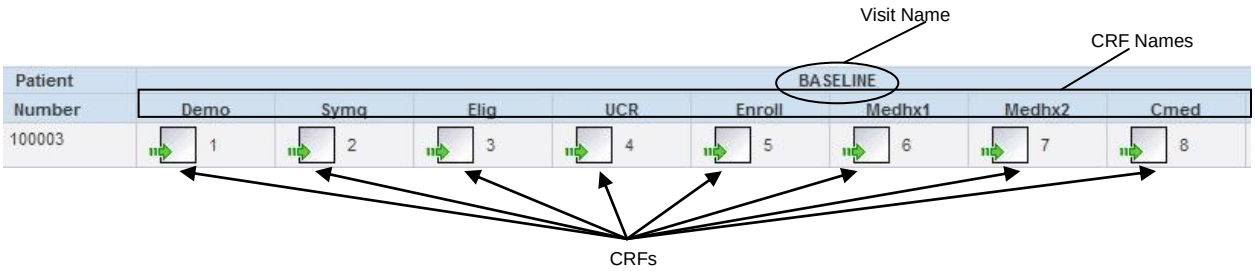
Patients: if the list of patients cannot fully be displayed, use the up and down caret signs, **Previous**, and **Next** options located in the upper left of the Casebook Spreadsheet to navigate across the groups of patients.

Casebook View: is the default Casebook or study a user is currently working in.

Visit: allows the user to select a visit from the dropdown list to view the CRFs associated with the Visit.

CRFs: if the number of columns viewable on screen is insufficient to show all CRFs for the visit selected, use (**<**) **Previous** or **Next** (**>**) in the upper right of the Casebook Spreadsheet, to navigate to visit CRFs that cannot be displayed in the current view.

Navigating within the Casebook Spreadsheet:



The information listed in the control section of the ***Casebook Spreadsheet*** corresponds to the spreadsheet view:

Visit Name: displays the current Visit Name. In the above example, **BASELINE** is displayed.

CRF Names: the CRFs associated with the Visit are displayed under the Visit Name.

CRFs: the CRFs for the patient row are displayed with their appropriate icon. The CRFs can represent Empty CRFs or Entered CRFs.

- Clicking on one of the CRF icons will allow the you to perform data entry on the CRFs for a given patient.
- The numbers beside the CRF icons act as sequence numbers for ordering and displaying the CRFs within a Casebook.

Data Entry Window (DEW)

- In RDC Onsite, the Data Entry Window (DEW) opens a pop-up window from the Casebook Surround Page.
- Users can have up to three DEWs open at a time, which operate independently of the Casebook Surround Page.

  The pop-up windows have the following functionality:

  - ***Ability to navigate between the RDC Onsite application tabs while the DEW windows are open.***

    This gives users the ability to access other areas of the application while the DEW is running without worrying about losing data or not having the ability to continue performing data entry while browsing the application.

  - ***All pop-up windows opened will remain active until the window is closed.***

    Each of these pop-up windows will display a unique name displayed in the Internet Window Header and also in the Windows Taskbar at the bottom of the screen:

RDC Onsite: Patient Casebooks - Windows Internet Explorer provided by Comcast
RDC Onsite DE: 100002, BASELINE, DEMO - Windows Internet Explorer provided by Co...
http://rt7.cceb.upenn.edu/olsa/oc/rdcOpenHtmlCrf.do?vobj=RdcMPCasebookCrfDetailsVO1&ppid=68917615&rdciid=19585
ORACLE RDC Onsite: Data Entry
RDC Onsite DE: 100003, BASELINE, DEMO - Windows Internet Explorer provided by Co...
http://rt7.cceb.upenn.edu/olsa/oc/rdcOpenHtmlCrf.do?vobj=RdcMPCasebookCrfDetailsVO1&ppid=68917715&rdciid=0&crfr
ORACLE RDC Onsite: Data Entry

In the example above the farthest window is the Casebook Surround Page, the middle window is the Baseline DEMO form for patient 100002, and the closest window is the Baseline DEMO form for patient 100003.

Opening a Data Entry Window (DEW):

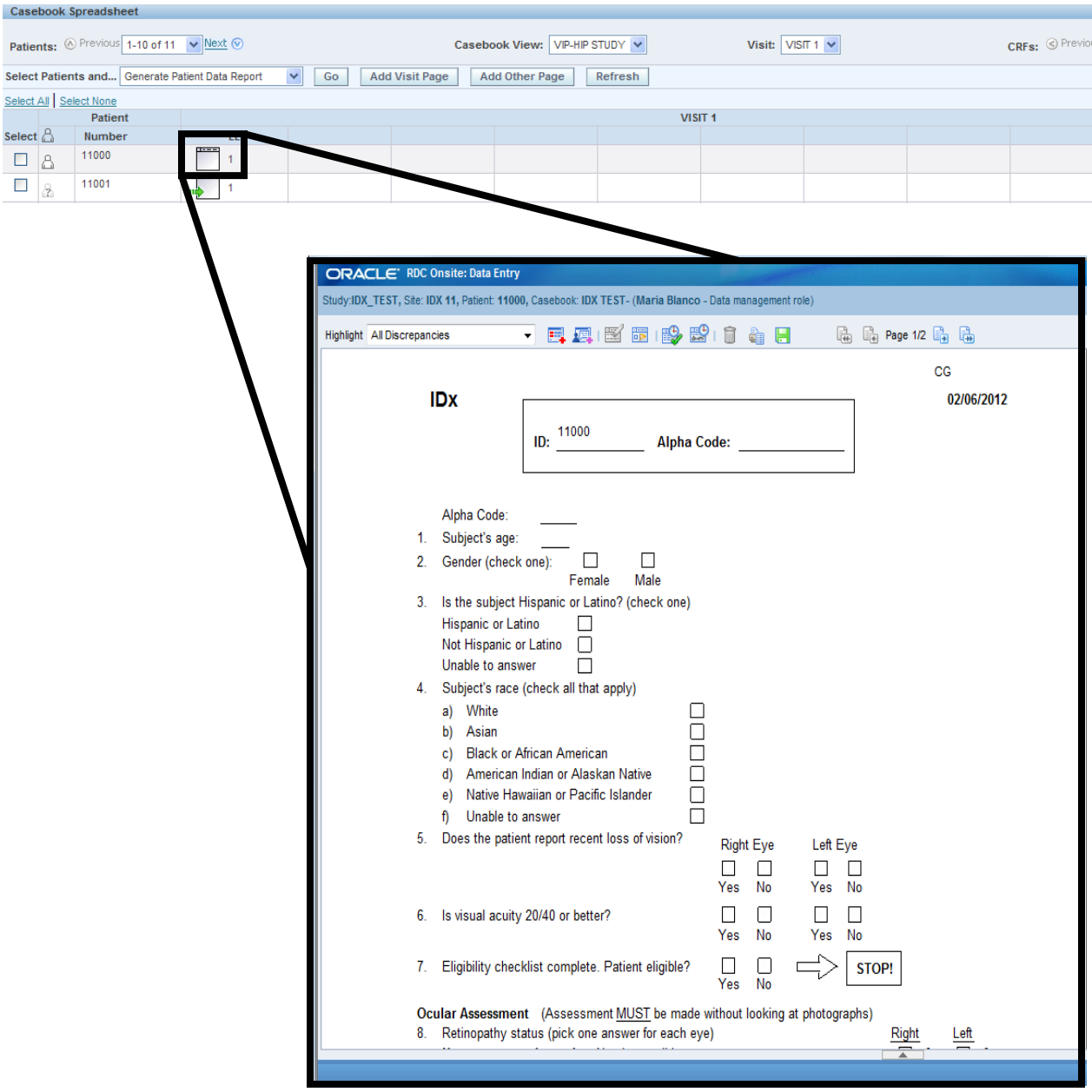
1. Click on a CRF icon from either the ***Casebook Page*** or the ***Review Page***.

Placeholder or ***Empty CRF***:

The Casebook Spreadsheet is the only section of RDC Onsite that displays empty CRF icons. These icons symbolize a CRF that is empty and awaiting data entry.

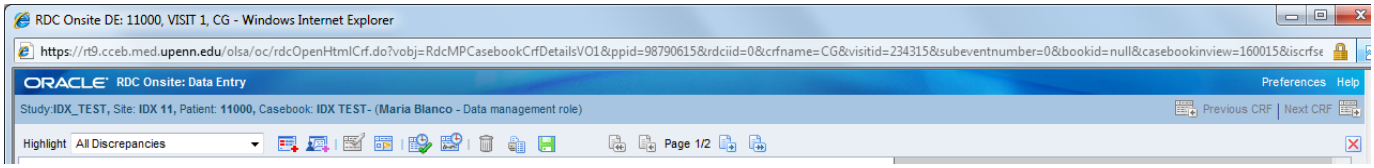
2. Click an empty CRF icon in the Casebook Spreadsheet to open the pop-up DEW and begin data entry.

Entered CRFs: Entered CRFs contain data and can be accessed from either the ***Casebook Page*** or the ***Review Page*** and opened in a DEW to update data.


Casebook Spreadsheet
Patients: Previous 1-10 of 11 Next
Casebook View: VIP-HIP STUDY
Visit: VISIT 1
CRFs: Previous 1-1 of 1 Next
Select Patients and... Generate Patient Data Report
Go
Add Visit Page
Add Other Page
Refresh
Select All | Select None
Patient
VISIT 1
Select
Number
11000
11001
ORACLE RDC Onsite: Data Entry
Study:IDX_TEST, Site: IDX 11, Patient: 11000, Casebook: IDX TEST- (Maria Blanco - Data management role)
Highlight All Discrepancies
Page 1/2
CG
IDx
02/06/2012
ID: 11000
Alpha Code:
Alpha Code:
1. Subject's age:
2. Gender (check one):
Female
Male
3. Is the subject Hispanic or Latino? (check one)
Hispanic or Latino
Not Hispanic or Latino
Unable to answer
4. Subject's race (check all that apply)
a) White
b) Asian
c) Black or African American
d) American Indian or Alaskan Native
e) Native Hawaiian or Pacific Islander
f) Unable to answer
5. Does the patient report recent loss of vision?
Right Eye
Left Eye
Yes
No
Yes
No
6. Is visual acuity 20/40 or better?
Yes
No
Yes
No
7. Eligibility checklist complete. Patient eligible?
Yes
No
STOP!
Ocular Assessment (Assessment MUST be made without looking at photographs)
8. Retinopathy status (pick one answer for each eye)
Right
Left

Data Entry Window (DEW) toolbar:

DEWs have a standard toolbar to facilitate work within the CRF:


RDC Onsite DE: 11000, VISIT 1, CG - Windows Internet Explorer
https://rt9.cceb.med.upenn.edu/olsa/oc/rdcOpenHtmlCrf.do?vobj=RdcMPCasebookCrfDetailsVO1&ppid=98790615&rdciid=0&crfname=CG&visitid=234315&subeventnumber=0&bookid=null&casebookinview=160015&iscrfse
ORACLE RDC Onsite: Data Entry
Preferences Help
Study:IDX_TEST, Site: IDX 11, Patient: 11000, Casebook: IDX TEST- (Maria Blanco - Data management role)
Previous CRF | Next CRF
Highlight All Discrepancies
Page 1/2

The DEW toolbar icons are described below:

Icon	Description	Function
	Add Discrepancy	The Add Discrepancy window opens.
	Investigator Comment	The Add/Update Investigator Comment window opens.
	Delete Row	The Delete Row dialog opens.
	Blank Flag Tool	The CRF Blank Selection(s) Processing dialog opens.
	Verification History	The Verify CRF window opens.
	Approval History	The Approve CRF window opens.
	Delete CRF	The Delete CRF window opens.
	Print	The Print options for the local user open.
	CRF Help	The optional CRF Help provided by your sponsor, opens.
	Save	RDC Onsite saves the CRF and displays a confirmation message.
	Previous CRF	Navigate to the previous CRF. This link appears only if a CRF is opened from the Casebooks Page. The link is disabled in the first CRF in a visit for a patient.
	Next CRF	Navigate to the next CRF. This link appears only if a CRF is opened from the Casebooks Page. The link is disabled in the last CRF in a visit for a patient.
	Close	The CRF and the DEW closes.

The DEW toolbar are there to assist you in performing data entry. The icons will be described in the sections of this Manual where their functions are utilized during data entry.

> ***TIP***: A few of the icons above require additional study privileges and may or may not function based on a users assigned role.

Navigating within the Case Report Form (CRF):

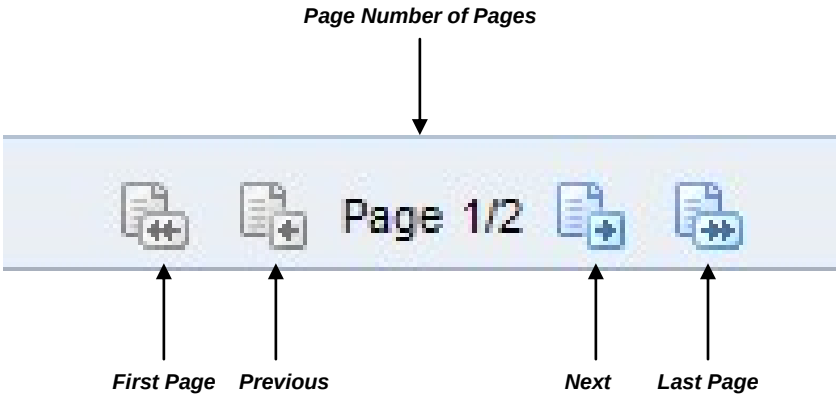
The Case Report Forms (CRFs) within the Data Entry Window (DEW) are replicas of the paper based study CRFs.

General layout of the CRFs within the DEW:

Vertical Scrollbar: Right of the open window if the CRF is too long to fit within the open DEW.

Horizontal Scrollbar: Bottom of the open window if the CRF is too wide to fit within the open DEW.

Page Navigation: In the DEW toolbar, if a CRF has multiple pages. The number of the current page is displayed against the total number of CRF pages. Navigate using the **Next**, **Previous**, or **Last Page** icons. See below:



General Data Entry with a Data Entry Window (DEW):

Using the Keyboard:

Tab: Move the cursor to the next data field available for data entry. The opened field will be outlined in gray.

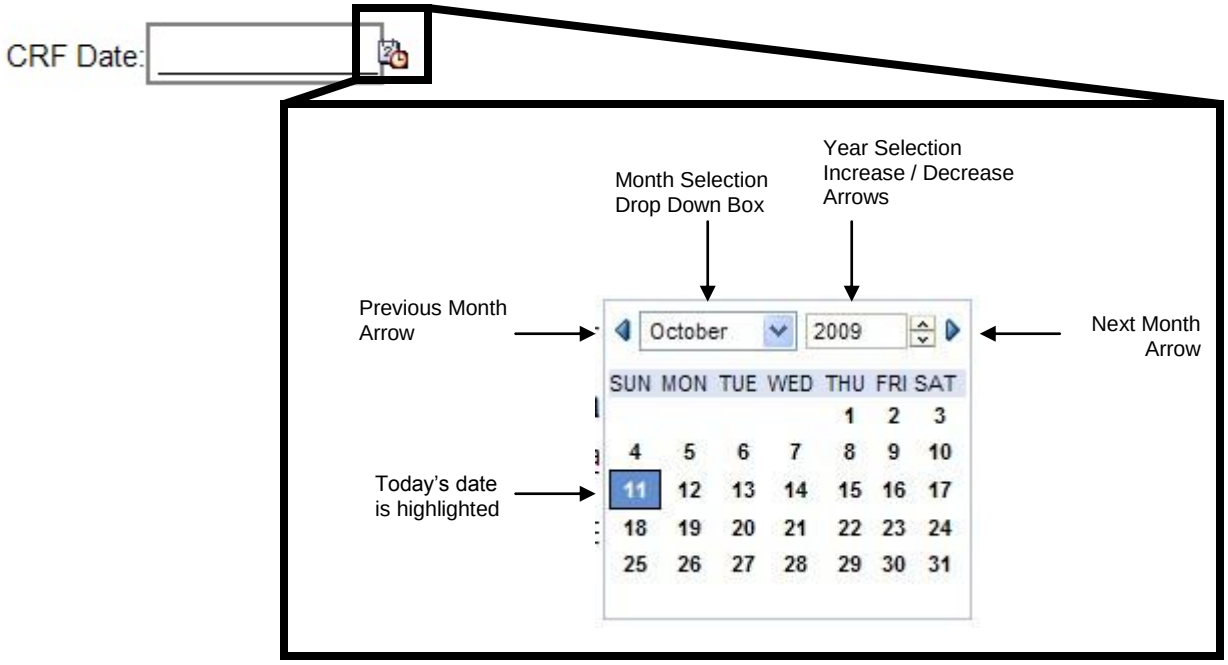
Shift Tab: Move the focus to the previous data entry field. The opened field will be outlined in gray.

Spacebar: Toggle a checkbox field on or off.

Using the Mouse:

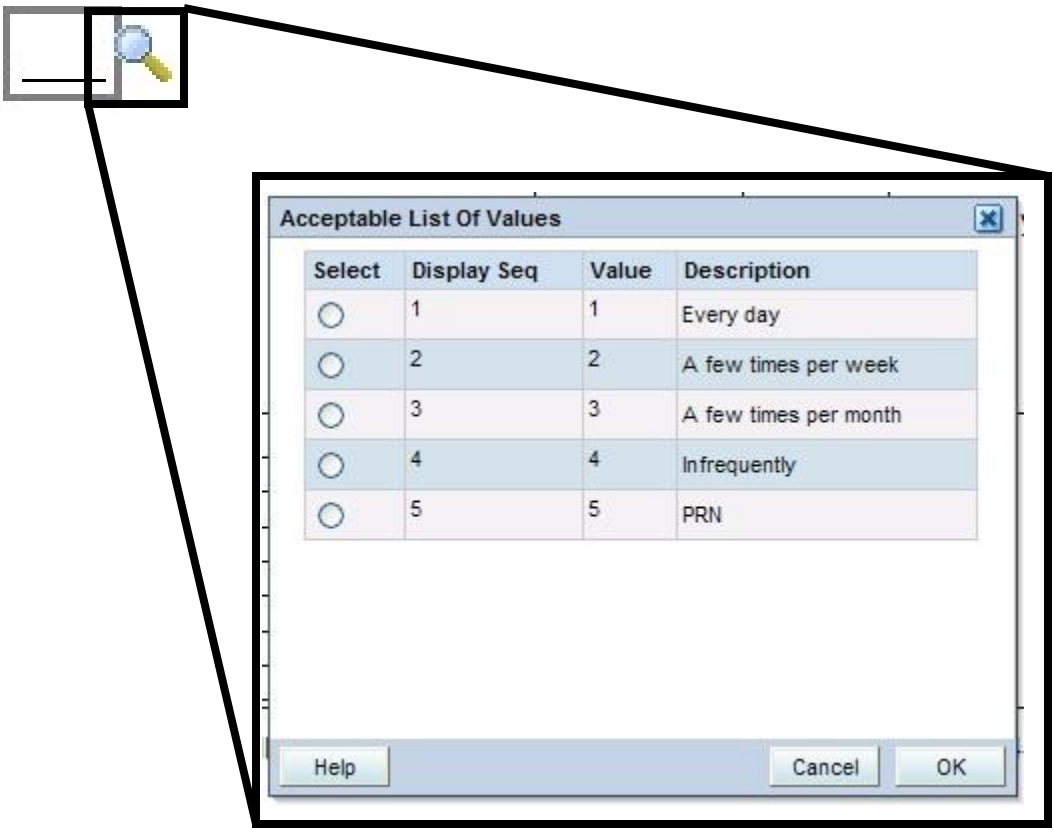
Left Click: Open the field for data entry. The opened field will be outlined in gray.

Date Fields: Click on the calendar icon to the right of the opened field to access the pop-up calendar window:


CRF Date:
Month Selection Drop Down Box
Year Selection Increase / Decrease Arrows
Previous Month Arrow
Next Month Arrow
Today's date is highlighted
October
2009
SUN MON TUE WED THU FRI SAT
1 2 3
4 5 6 7 8 9 10
11 12 13 14 15 16 17
18 19 20 21 22 23 24
25 26 27 28 29 30 31

- Navigate to the appropriate *Month* (Month Selection Drop Down Box) and *Year* (Year Selection Increase / Decrease Arrows).
- Click on the Day and the date will populate in the field.
- or manually enter the date in the opened date field instead of opening the calendar pop-up window.

List of Values: Some fields have lists of study-defined values associated with the data entry field. A magnifying glass icon at the right of the opened field indicates the field has an associated List of Values (LOV). Click on the icon to access a pop-up LOV window:



- Click the radio button in the SELECT column for the answer of a ROW.
- The “VALUE” field in the LOV pop-up indicates the numeric value of the answer associated with the paper-based CRF (the small number to the right of a check box).
- or manually enter this number in the opened field instead of using the LOV pop-up window.

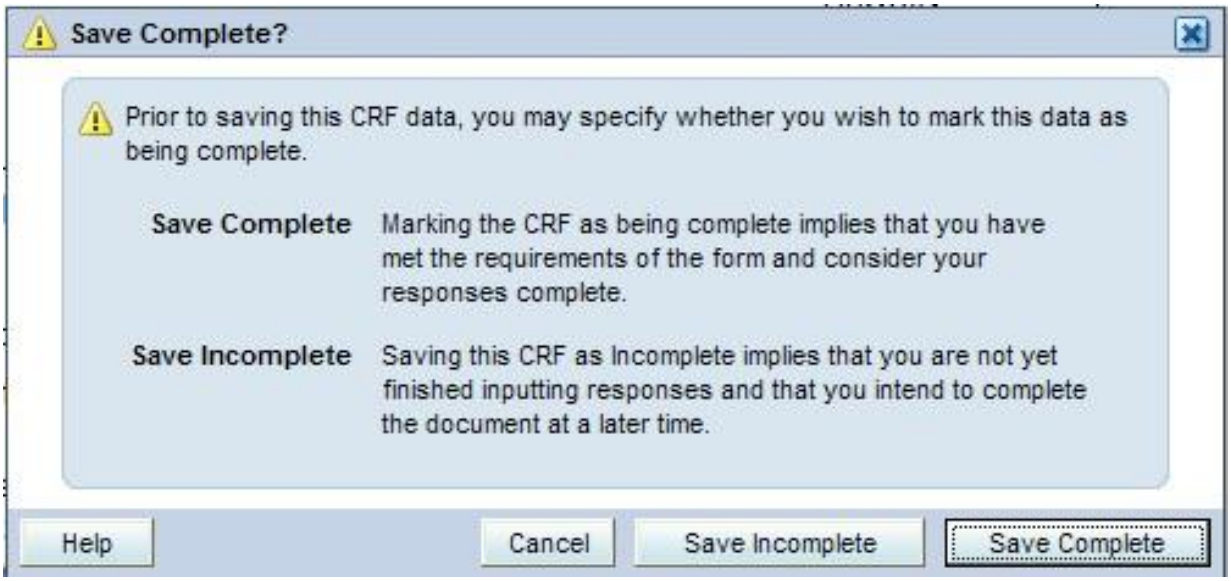
Entering data in a CRF:

All CRFs – either Empty or Entered – contain basic study related information: Study Name, Logo, Site Name / Number, Patient Identification Number (PID), CRF Name, etc. You are only required to enter responses to the remaining CRF questions.

To enter data in a CRF:

1. Click on a field to enter or update information.
2. Enter the data.
3. Use the Keyboard or Mouse to navigate from the field after adding or changing a value.
4. After all of the data has been entered or updated, click on the Save Data Icon in the toolbar.

Confirm ***Save Data*** using the ***Save Complete*** pop-up window:


Save Complete?
Prior to saving this CRF data, you may specify whether you wish to mark this data as being complete.
Save Complete
Marking the CRF as being complete implies that you have met the requirements of the form and consider your responses complete.
Save Incomplete
Saving this CRF as Incomplete implies that you are not yet finished inputting responses and that you intend to complete the document at a later time.
Help
Cancel
Save Incomplete
Save Complete

5. Select ***Save Incomplete*** or ***Save Complete***:

   Save Complete – indicates that all of the data for a CRF has been entered.

   - Selecting this option if all the data fields for the CRF are complete.
   - Discrepancy management will run on the CRF and highlight any discrepancies in red. ***Any data changes made to a field after the CRF has been saved as complete will need to be documented in Audit Trail Dialogue boxes indicating the "Reason for Change" (described in 5c of this section of the Manual).***

   Save Incomplete – indicates that data has been entered but is *not considered complete*.

   - Select this option to save entered data to the study database, and that you intend to complete the document at a later time.
   - The Audit Trail Dialogue does not pop-up for any data changes or updates.

Navigating between CRFs:

While in an open Data Entry Window (DEW), you can move from one CRF to another without closing the DEW and reopening a new CRF:

1. Click on the ***Previous CRF*** or ***Next CRF*** links in the upper right corner:

The ***Previous CRF*** or ***Next CRF*** opens in the same DEW and will move you backward or forward through the CRFs displayed in the Casebook Spreadsheet.

These navigational links are restricted to CRFs for a single patient and visit, and these links are only available to CRFs opened from the Casebook Page.

To change patients or visits:

Open additional DEWs for the patients and/or visits:

2. Select the CRF icon from the Casebook Spreadsheet, or

3. Close the current DEW (click the red X in the toolbar) and open up a new DEW.

Updating Existing Data in a CRF:

Data updates for existing CRF data can be performed from either the Casebook Page or the Review Page within the RDC Onsite application.

To update a data field:

1. Enter the CRF to be updated.

2. Select the data field to be updated.

3. Change the value of the response.

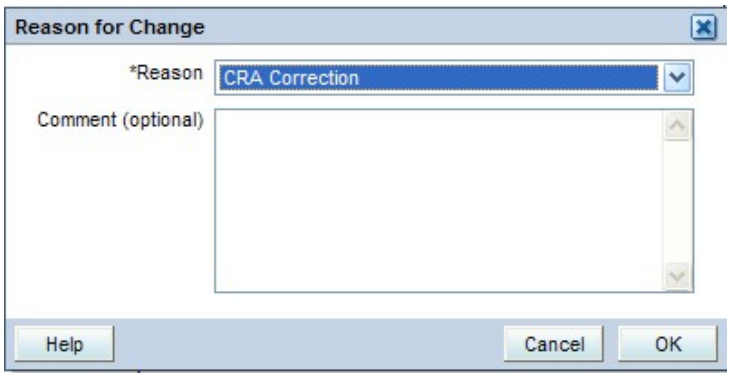
4. Continue data entry if multiple values need to be entered or updated, or

   click the Save button in the toolbar.

Depending on the status of the CRF, RDC Onsite will respond accordingly:

CRF Previously Saved Incomplete – the system will accept the updates and prompt you to save the data using either the ***Save Complete*** or ***Save Incomplete*** options.

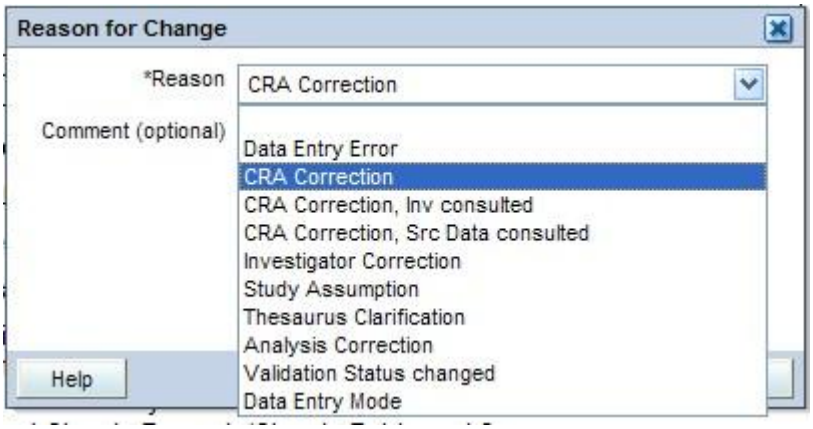
CRF Previously Save Complete – the ***Reason for Change*** pop-up window will open:



The ***Reason for Change*** is used as a way to provide additional information regarding changes made to data that has been ***Saved Complete***. This additional information, along with the prior value and updated value, gets added to the Audit Trail history and allows for a more comprehensive understanding for data changes made at the site level.

To complete the Reason for Change:

1. Click the downward arrow beside the **Reason** field to view a dropdown list:



2. Select a reason from the dropdown list to populate the **Reason** field. This is a mandatory field and RDC Onsite will not accept the change without a **Reason**.

3. Enter a comment in the **Comment** text box. Use this comment field to provide additional information, if needed, about the change being made.

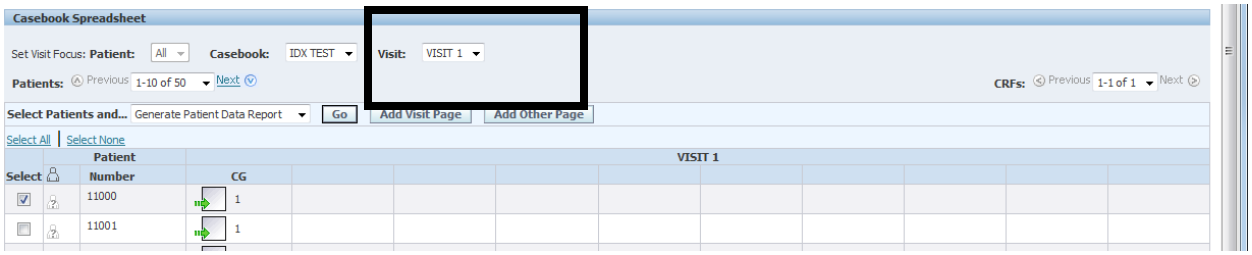
4. Click **OK** to process the data change.

Inserting CRFs – Additional CRFs and Unplanned CRFs:

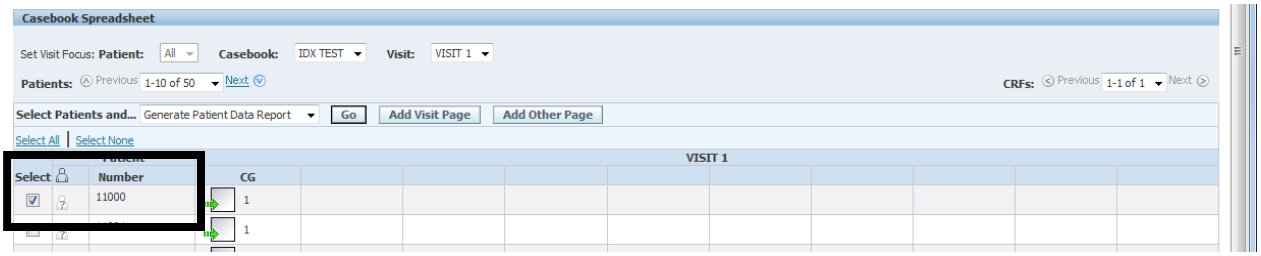
Depending on the needs of a study, you can add additional CRFs or add unplanned CRFs to a visit.

To add additional CRFs:

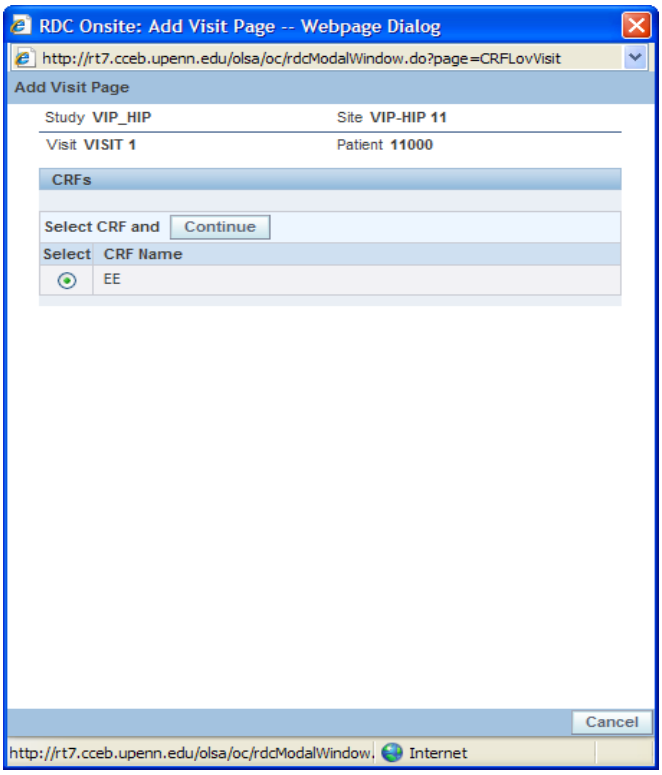
1. Select a visit value from the Visit dropdown list in the control box area of the Casebook Spreadsheet.


Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: IDX TEST Visit: VISIT 1
Patients: Previous 1-10 of 50 Next
CRFs: Previous 1-1 of 1 Next
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page
Select All | Select None
Patient
VISIT 1
Select Number CG
11000 1
11001 1

2. Check the patient **Select** box to select a patient in the Casebook Spreadsheet.


Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: IDX TEST Visit: VISIT 1
Patients: Previous 1-10 of 50 Next
CRFs: Previous 1-1 of 1 Next
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page
Select All | Select None
VISIT 1
Select Number CG
11000 1

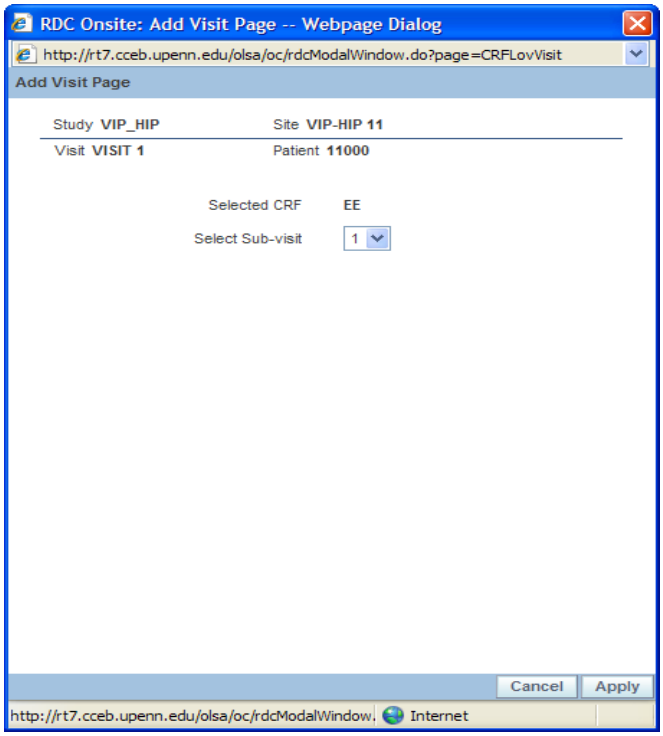
3. Click the ***Add Visit Page*** button in the control box section. The Add Visit Page dialog box opens, listing all the planned CRFs for the current visit, patient, study, and site. TIP: Adding pages is not an option for IDX.



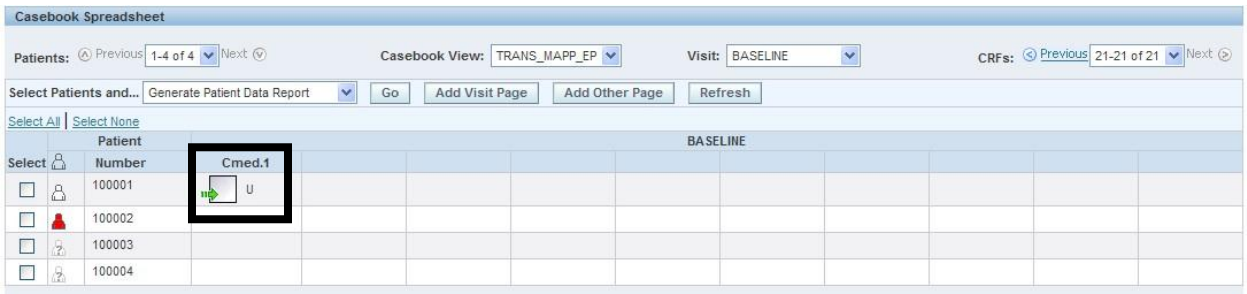
4. Select a CRF by clicking on the radio button beside the CRF name.

5. Click **Continue** to proceed to the next dialog.

6. Select a sub-visit from the dropdown list to add to the current visit. The new CRF is identified accordingly. For example if the sub-visit is 1 and the CRF is CMED, the new visit page is CMED.1.



7. Return to the Casebook Spreadsheet to view the new, empty CRF icon in the designated patient row and CRF column. Notice that a new CRF column may have been inserted and labeled with both the CRF name and the sub-visit number.



8. Click the new CRF icon to open the CRF in Data Entry Window (DEW).

9. Enter data and save the CRF.

- The patient makes an unscheduled visit – examples: Unplanned Blood Draws. In this case, the sub-visit number correlates to a visit that happens after Visit X and Before Visit Y.

Discrepancy Management

Discrepancy management refers to an electronic process that systematically addresses data entry discrepancies within study CRFs. Data entered into the RDC Onsite application is evaluated against a set of study-defined expectations for each response field (answer on the CRFs). The application will trigger discrepancy management and create displayable messages regarding the discrepancy for reconciliation.

Discrepancy Types

There are two types of discrepancies that operate within the RDC Onsite application – ***Simple (Univariate)*** and ***Complex (Multivariate)*** discrepancies:

Simple (Univariate) – Discrepancies that are dependent on the value of a single data point.

- Simple discrepancies usually relate to the format of the data entered, to missing data in required fields, or to an unexpected value entered into a defined field.
- Simple discrepancies are triggered in real time and cause a dialogue box to be displayed while the user is performing data entry.

Example – Leaving an Inclusion or Exclusion criteria question blank on the Eligibility form.

Complex (Multivariate) – are discrepancies that are dependent on two or more data point values, which can be within a single CRF or across multiple CRFs and / or visits.

- Complex discrepancies relate to missing data, to data that does not correlate with other data within a CRF or across CRFs, or to significant differences in data across time for patient safety.
- Complex discrepancies are triggered when a CRF is saved, causing fields and icons to be flagged in red.

Example – The system automatically calculates BMI from entered weight and height values, if a weight value is missing the calculation cannot trigger.

Discrepancy Status

There are two discrepancy statuses that operate with the RDC Onsite application – **Open Discrepancies** and **Closed Discrepancies**:

Discrepancy Status CRF Icons

Icon	CRF Label	Description
	No Discrepancies	There are no Other or Active discrepancies associated with the CRF. (Note that there may be closed discrepancies associated with the CRF.)
	Active	There is at least one Active discrepancy in the CRF, to be addressed by you.
	Other	There is at least one discrepancy that must be addressed by a user in a role other than yours.

Open Discrepancies appear in two formats:

- **Active** – a discrepancy that requires action or resolution based upon data that has been entered and validated. These discrepancies produce red icons and highlight the discrepant data in red.
- **Other** – a discrepancy that requires action or resolution based upon data that has been reviewed and queried by another user – DCC Data Mangers (DM) typically. Other discrepancies also indicate coding dictionary errors on entered data – Adverse Event (AE) Coding in Progress. These discrepancies produce yellow icons and highlight the discrepant data in yellow.

Closed Discrepancies represent discrepancies that have been resolved:

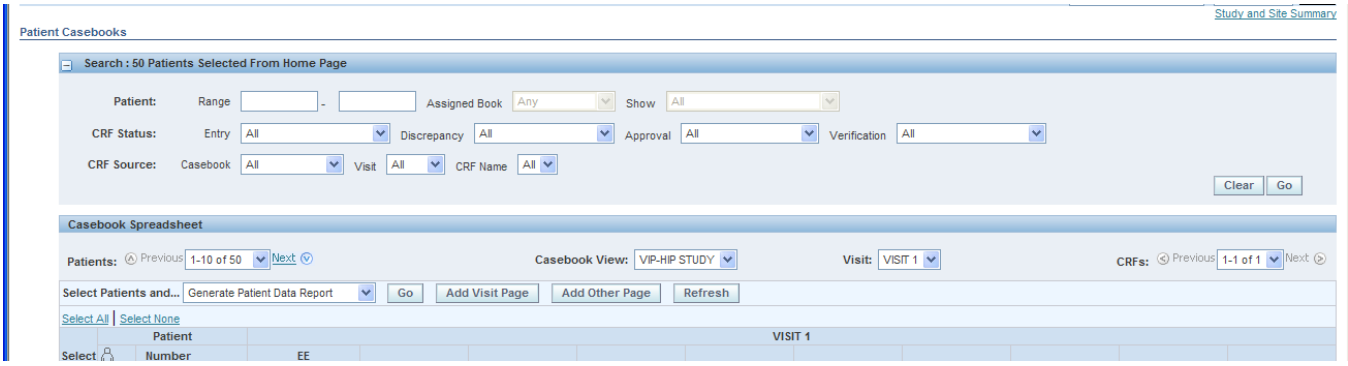
- ***Resolution of discrepancy*** – data updated or modified in accordance with edit checks. The red highlight of the field will disappear if a discrepancy has been resolved.
- ***Affirmation of discrepancy*** – an open discrepancy based on "unexpected" data results entered into CRF fields can be confirmed to be valid values and the discrepancy can be "Closed with no resolution". These fields will be highlighted in green.

Reviewing Discrepancies

In this section, finding and reviewing discrepancies will be discussed. Discrepancies can be reviewed from the two ***Surround Pages*** (*Casebook Page and Review Surround Page*) differently, to identify CRFs containing active discrepancies:

Casebook Page Surround Discrepancy Review:

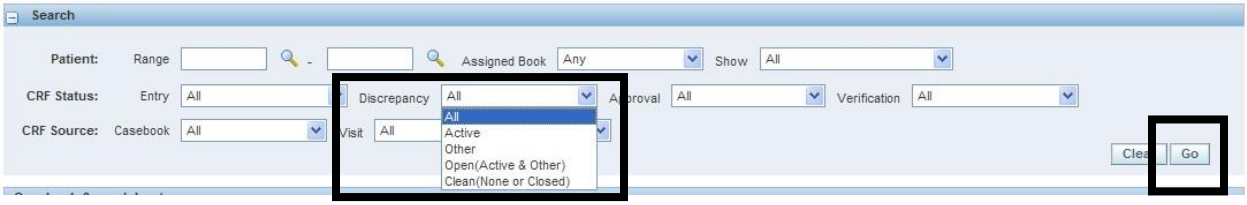
The Casebook Surround Page organizes CRF icons in patient rows and CRF columns in casebook order. This organization can be useful in managing discrepancies on a patient-by-patient or visit-by-visit basis.


Study and Site Summary
Patient Casebooks
Search : 50 Patients Selected From Home Page
Patient: Range Assigned Book Any Show All
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go
Casebook Spreadsheet
Patients: Previous 1-10 of 50 Next
Casebook View: VIP-HIP STUDY
Visit: VISIT 1
CRFs: Previous 1-1 of 1 Next
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page Refresh
Select All | Select None
Patient
VISIT 1
Select
Number
EE

To find patients with active discrepancies:

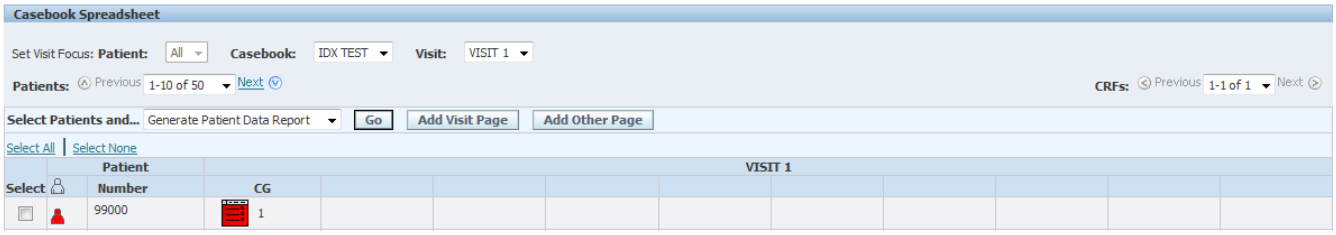
1. Expand the Search section pane to specify a search for patients with active discrepancies.

2. Select ***Open (Active & Other)*** from the discrepancy drop-down of the CRF Status row.



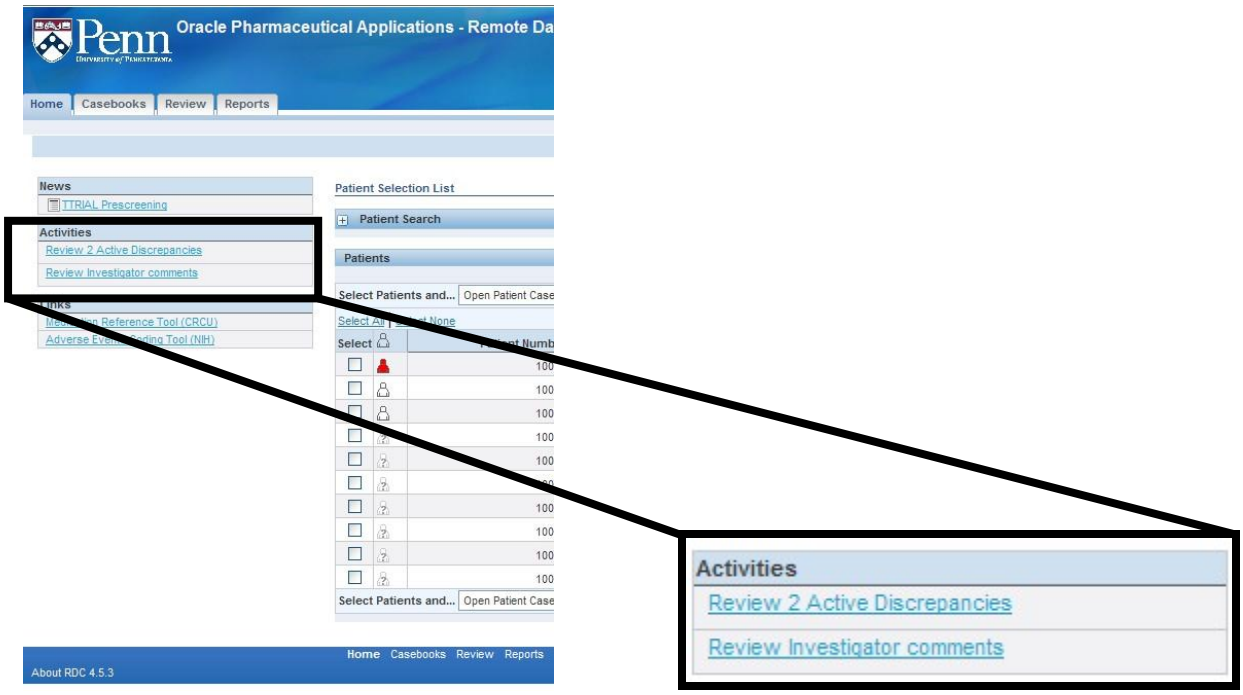
3. Click **Go**.

The Casebook Spreadsheet will display only those CRF icons with active discrepancies.

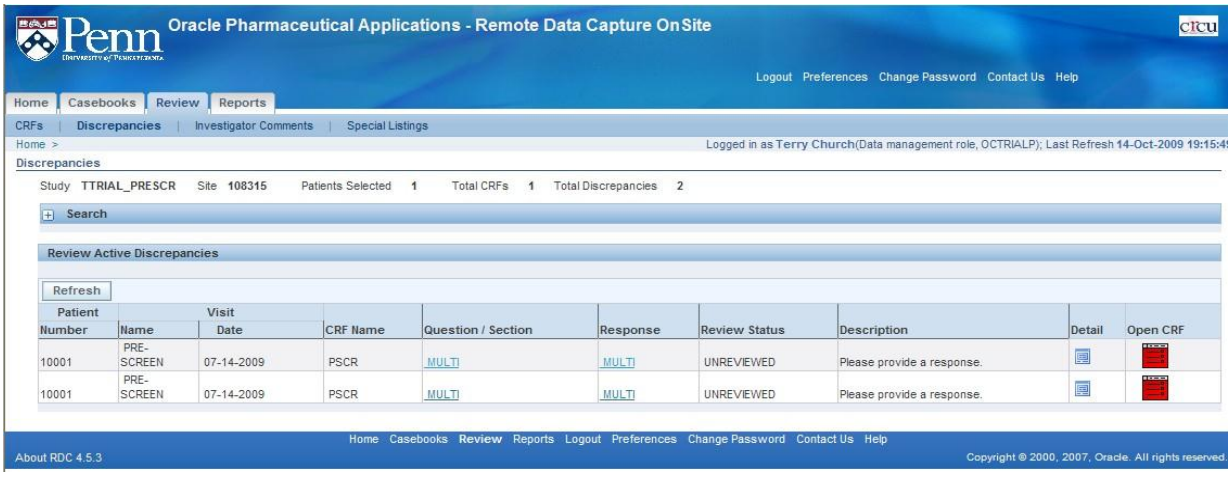

Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: IDX TEST Visit: VISIT 1
Patients: Previous 1-10 of 50 Next
CRFs: Previous 1-1 of 1 Next
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page
Select All | Select None
Patient
VISIT 1
Select
Number
CG
99000
1

Review Page Surround for Discrepancy Review

The Review Discrepancies Page is especially useful in reviewing discrepancies across CRFs. To access this page, click on the hyperlink **Review [#] Active Discrepancies** from the **Activities** section on the Home Page.



This hyperlink will open the ***Review Active Discrepancies*** view of the ***Review Surround Page***, listing all active discrepancies across all patients and CRFs for the site.



In the case above: 1 Patient, 1 CRF, 2 Total Discrepancies.

Working with the Review Page

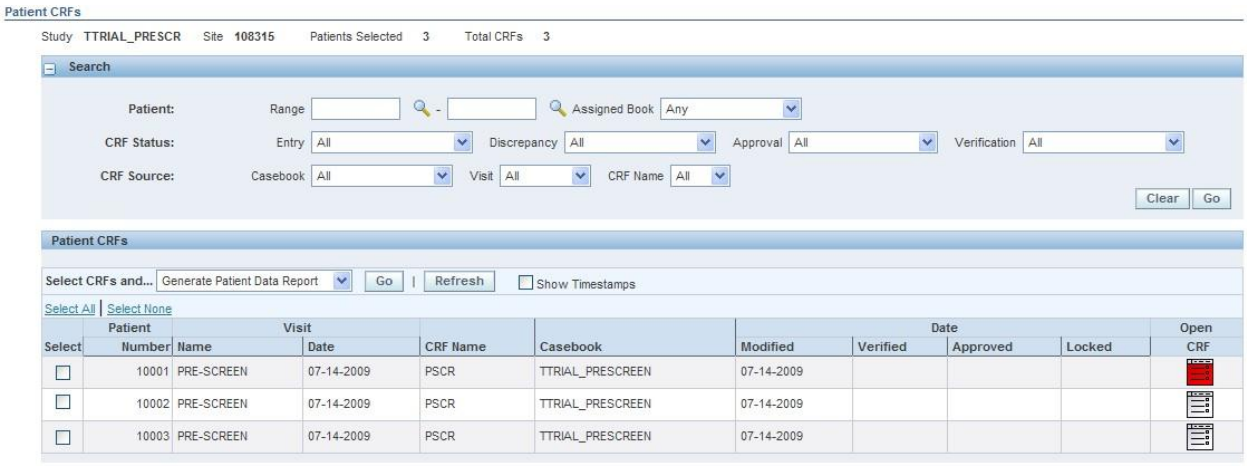
The Review Page Surround provides easy access to review data entered in RDC Onsite via one of the 4 topical areas:

CRFs: View Audit Trail History about CRFs that have been entered and saved.

1. Use the Search pane of the Patient CRFs to view a sub-set of data or all entered data.

2. Click **Go**

The Patient CRFs section will display information about the Search criteria. The screen below shows that for this study there are 3 current patients with data.


Patient CRFs
Study TTRIAL_PRESCR Site 108315 Patients Selected 3 Total CRFs 3
Search
Patient: Range - Assigned Book Any
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go
Patient CRFs
Select CRFs and... Generate Patient Data Report Go | Refresh Show Timestamps
Select All | Select None
Patient Visit Date Open
Select Number Name Date CRF Name Casebook Modified Verified Approved Locked CRF
10001 PRE-SCREEN 07-14-2009 PSCR TTRIAL_PRESCREEN 07-14-2009
10002 PRE-SCREEN 07-14-2009 PSCR TTRIAL_PRESCREEN 07-14-2009
10003 PRE-SCREEN 07-14-2009 PSCR TTRIAL_PRESCREEN 07-14-2009

The Patient CRFs section displays the following data in the columns:

Patient Number: Patient numbers listed in descending order.

Visit (Name & Date): Visit Name and Date CRFs entered.

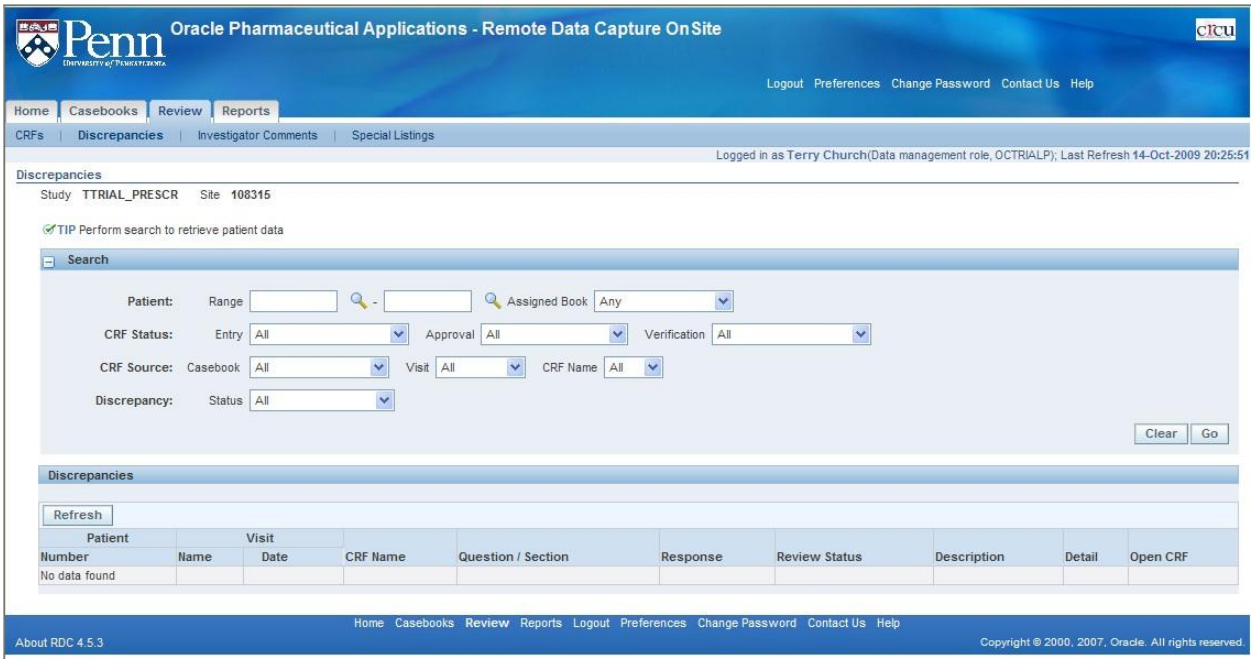
CRF Name: CRFs listed according to the order within a Casebook; in this case there is only one CRF for this visit.

Casebook: Casebook or Study information

Date (Modified, Verified, Approved, & Locked): Dates of the most recent modification, verification, approval, and lock. Some of these dates may never be populated depending upon study use.

Open CRF: Hyperlink to a Data Entry Window (DEW) to update data or review discrepancies.

Discrepancies: Access to Search Discrepancies.


Oracle Pharmaceutical Applications - Remote Data Capture OnSite
Logout Preferences Change Password Contact Us Help
Home Casebooks Review Reports
CRFs Discrepancies Investigator Comments Special Listings
Logged in as Terry Church(Data management role, OCTRIALP); Last Refresh 14-Oct-2009 20:25:51
Discrepancies
Study TTRIAL_PRESCR Site 108315
TIP Perform search to retrieve patient data
Search
Patient: Range Assigned Book Any
CRF Status: Entry All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Discrepancy: Status All
Clear Go
Discrepancies
Refresh
Patient Number
Visit Name
Visit Date
CRF Name
Question / Section
Response
Review Status
Description
Detail
Open CRF
No data found
Home Casebooks Review Reports Logout Preferences Change Password Contact Us Help
About RDC 4.5.3
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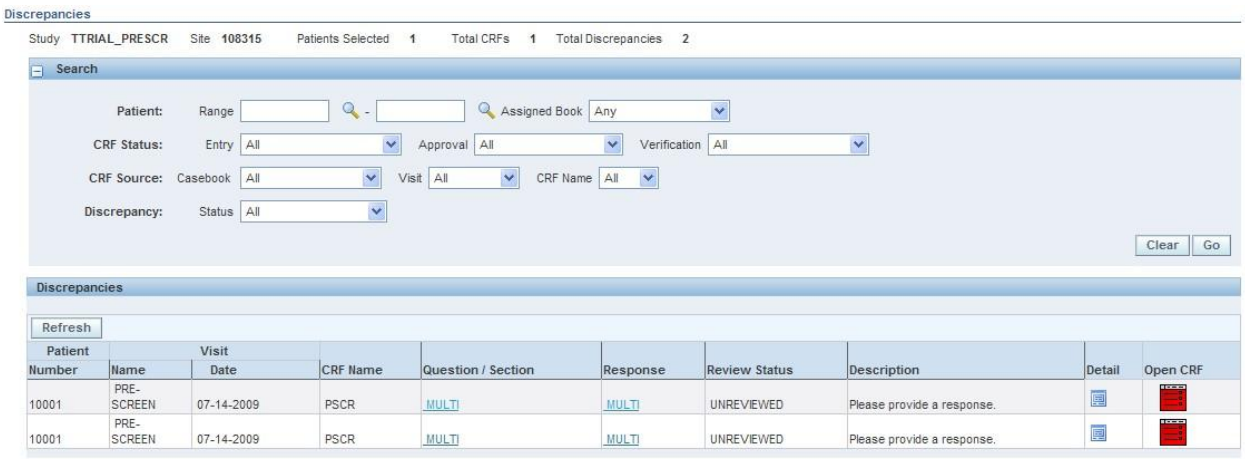
1. Use the Search section pane within Discrepancies to view a sub-set of data or all entered data.

2. Click **Go**

The Discrepancies section will display information about the Search selection criteria. The detail below shows that for this study there is 1 patient, 1 CRF, and 2 total discrepancies



The Discrepancies section displays the following data in the columns:

Patient Number: Patient number for the query; in this case there is one patient displayed on two rows.

Visit (Name & Date): Visit name and date of CRF entry.

CRF Name: CRF Name for the open discrepancies.

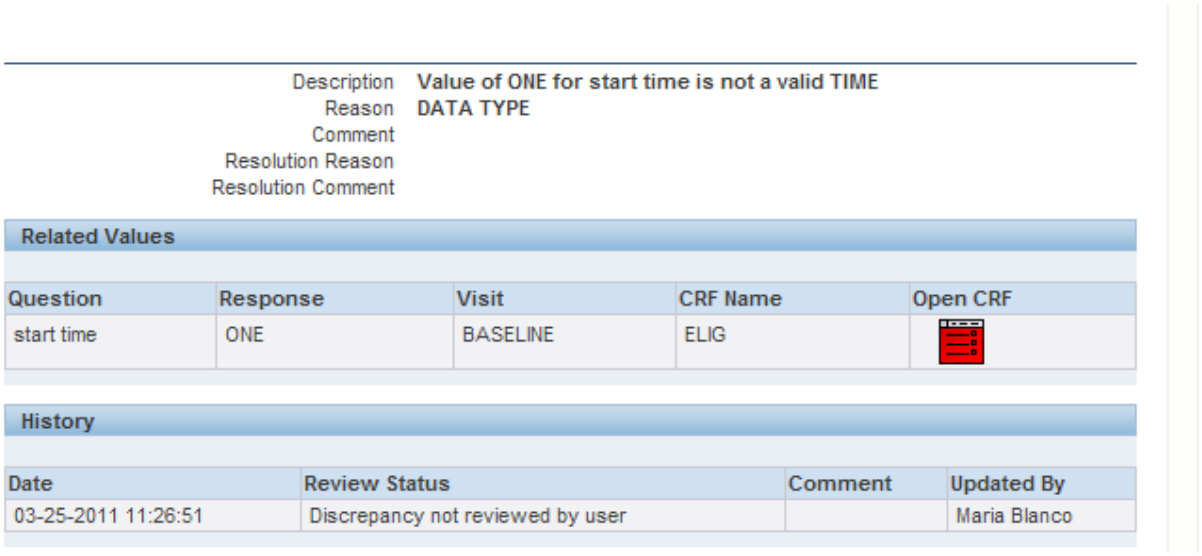
Question / Section: Hyperlink to open the Discrepancy Detail for more information.

Response: Hyperlink to view the Discrepancy Details for more information

Review Status: Display the discrepancies current review status.

Description: Display the discrepancy message.

Detail: Open a review window to view related values and discrepancy history without opening the CRF:



Description Value of ONE for start time is not a valid TIME
Reason DATA TYPE
Comment
Resolution Reason
Resolution Comment

Related Values

Question	Response	Visit	CRF Name	Open CRF
start time	ONE	BASELINE	ELIG	

History

Date	Review Status	Comment	Updated By
03-25-2011 11:26:51	Discrepancy not reviewed by user		Maria Blanco

Open CRF: Hyperlink to a Data Entry Window (DEW) to address the discrepancy or modify data.

Sort the displayed discrepancies by clicking on any column header:

Discrepancies

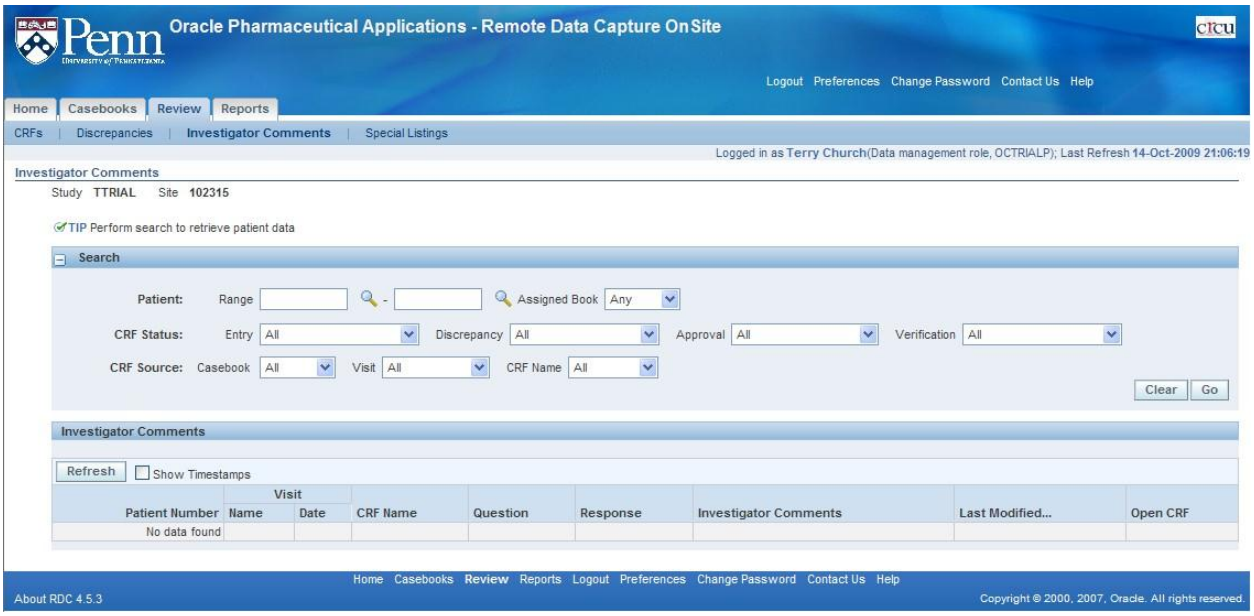
Refresh

Patient Number	Visit Name	Visit Date	CRF Name	Question / Section	Response	Review Status	Description	Detail	Open CRF
10001	PRE-SCREEN	07-14-2009	PSCR	MULTI	MULTI	UNREVIEWED	Please provide a response.		
10001	PRE-SCREEN	07-14-2009	PSCR	MULTI	MULTI	UNREVIEWED	Please provide a response.		

Sort or Search by:

- ***Patient*** to view a list of all discrepancies sorted by patient.
- ***Visit*** to view all discrepancies for a given ***Visit*** across patients.
- ***Review Status*** to view which discrepancies are currently open or currently in review.
- ***Description*** to find any view discrepancies based upon their error message.

Investigator Comments – View field level comments or notes that an Investigator, Monitor, or Reviewer deems appropriate to be included for a given value. This feature may or may not be used for a particular study.


Oracle Pharmaceutical Applications - Remote Data Capture OnSite
Logout Preferences Change Password Contact Us Help
Home Casebooks Review Reports
CRFs | Discrepancies | Investigator Comments | Special Listings
Logged in as Terry Church(Data management role, OCTRIALP); Last Refresh 14-Oct-2009 21:06:19
Investigator Comments
Study TTRIAL Site 102315
TIP Perform search to retrieve patient data
Search
Patient: Range Assigned Book Any
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go
Investigator Comments
Refresh Show Timestamps
Patient Number Visit Name Visit Date CRF Name Question Response Investigator Comments Last Modified... Open CRF
No data found
Home Casebooks Review Reports Logout Preferences Change Password Contact Us Help
About RDC 4.5.3
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1. Use the Search section pane within Investigator Comments to view a sub-set of data or all entered data.

2. Click **Go**

The Investigator Comments (if there are any used for the study) section displays the following data in the columns:

Patient Number: Patient number for the query; in this case there is one patient displayed on two rows.

Visit (Name & Date): View the associated visit name and date of CRF entry.

CRF Name: View the CRF Name of the Investigator Comment.

Question: Hyperlink to open the Investigator Comment Detail for more information.

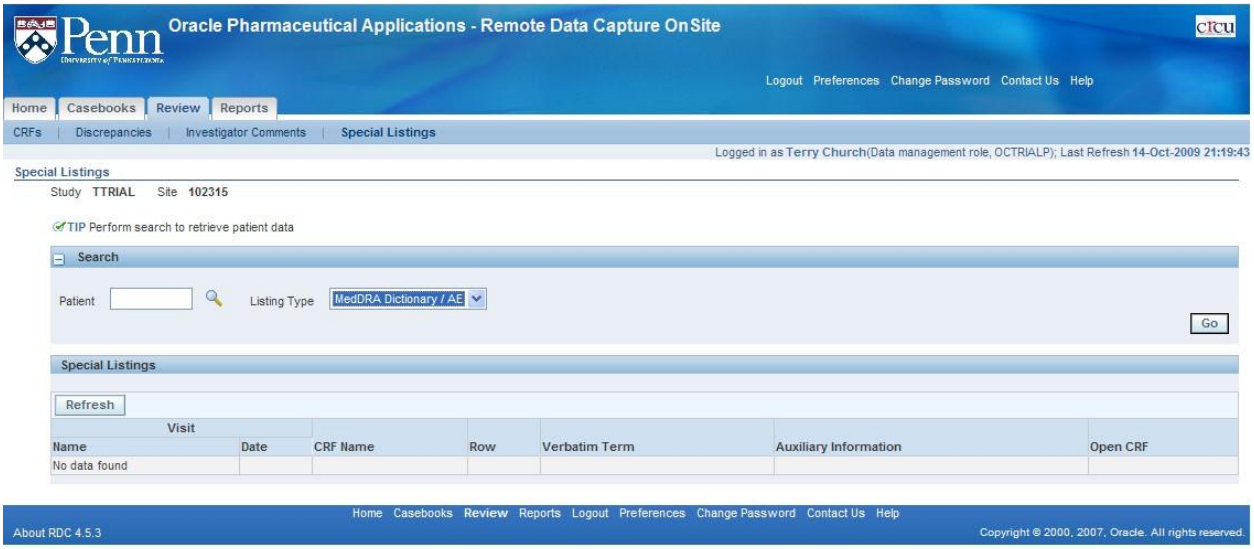
Response: Hyperlink to view the Investigator Comment detail for more information.

Investigator Comment: Display the associated comment for the Question.

Last Modified: Display the date the comment was last modified.

Open CRF: Open a DEW for the CRF and view the comment on the associated CRF.

Special Listings – View specialized questions. Examples may include Adverse Events or Concomitant Medications with coding errors that need to be reviewed and updated.

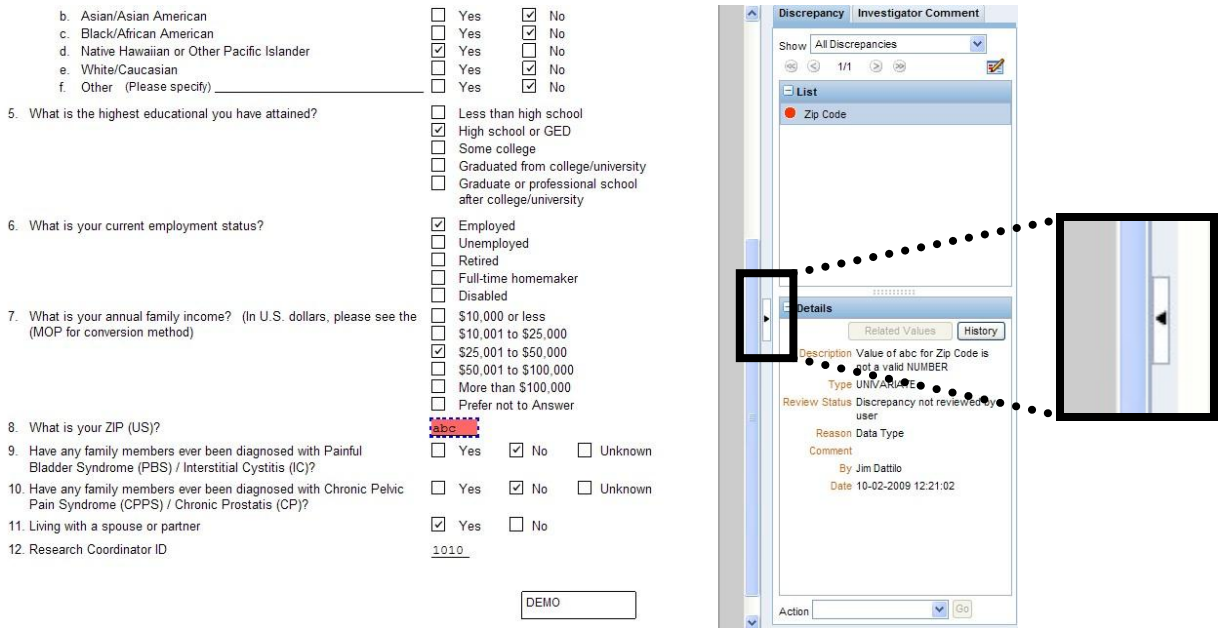


NOTE: Primarily, CRCU staff only use this area, therefore the functionality will not be described in detail.

Resolving Discrepancies

After a CRF with a discrepancy has been found, you will need to open it in a Data Entry Window (DEW). The CRFs with discrepancies can be opened from the Home Page Surround, the Casebook Page Surround, or the Review Page Surround as detailed in the previous sections.

- Use the ***Navigator Pane*** to review, in list format, all Discrepancies or Investigator Comments (if applicable for the study) for a CRF.
- By navigating through the list of Discrepancies or Investigator Comments, you simultaneously navigate through the associated fields in the CRF.



Using the Navigator Pane

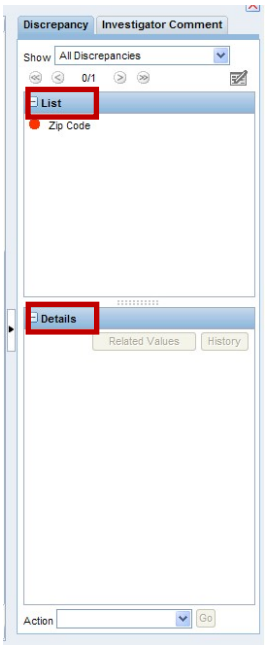
1. Click the arrow on the right edge of the DEW to open/close the ***Navigator Pane***:

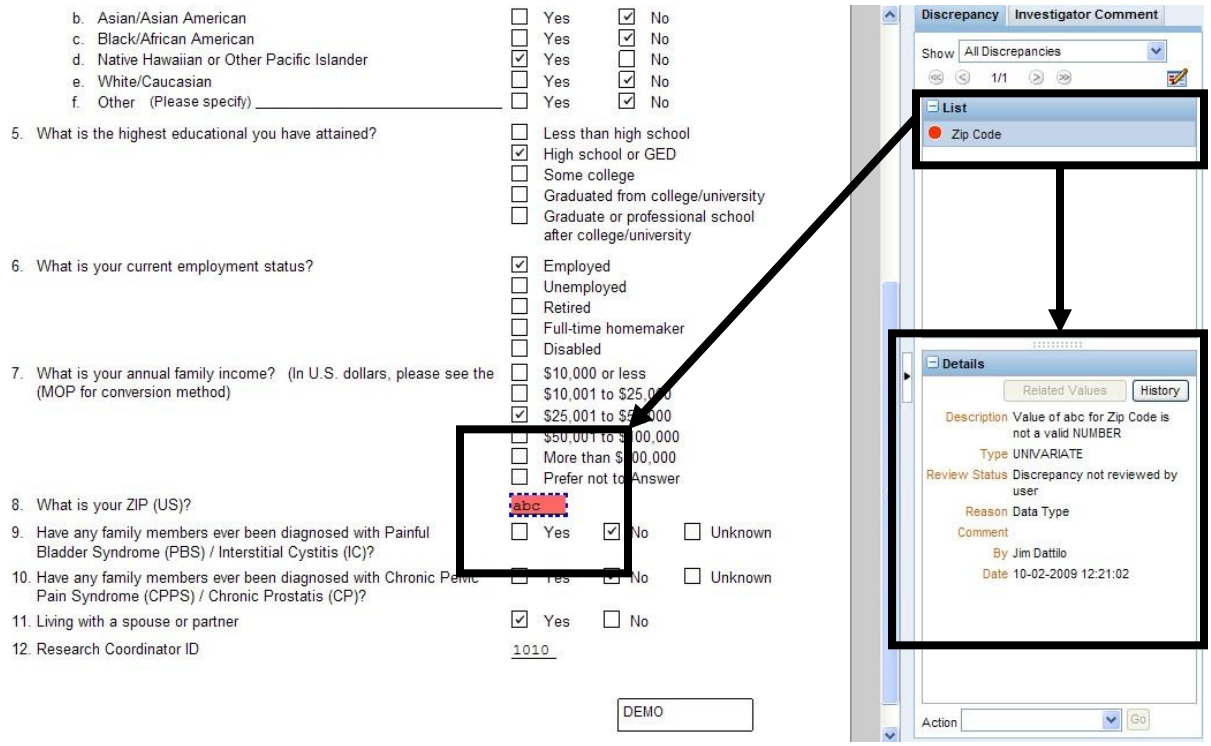
2. Select a tab, either ***Discrepancy Navigator*** or ***Investigator Comments*** Navigator.

There are two sub-panes of the Navigator: **List** and **Details**. These sub-panes help organize information and facilitate movement in the open CRF.

3. Click the nodes (**+** or **-**) next to the **List** or **Details** in the title bar of the sub-pane to collapse (**-**) or expand (**+**) the sub-pane windows.

- **List**: Lists discrepancies or investigator comments according to the tab selected. Click an item in the list to review the associated field within the CRF and activate the **Details** sub-pane.
- **Details**: View details of a selected discrepancy or investigator comment within this sub-pane. A scroll bar at the right edge of the sub-pane allows you to scroll through **Details**.





4. Click on an item in the **List** to view the **details**

Related Values opens a pop-up window listing any previously entered values for the same CRF at different visits to show values over time. In the example above, the button is not available meaning this field has no related values.

History opens a pop-up window listing the discrepancy history:

5. After the discrepancy has been reviewed, correct the data in the associated highlighted field appropriately.

A reason for change dialog box will appear.

6. Save the CRF and the discrepancy will automatically close.

Using the Navigator Pane to Respond to Discrepancies:

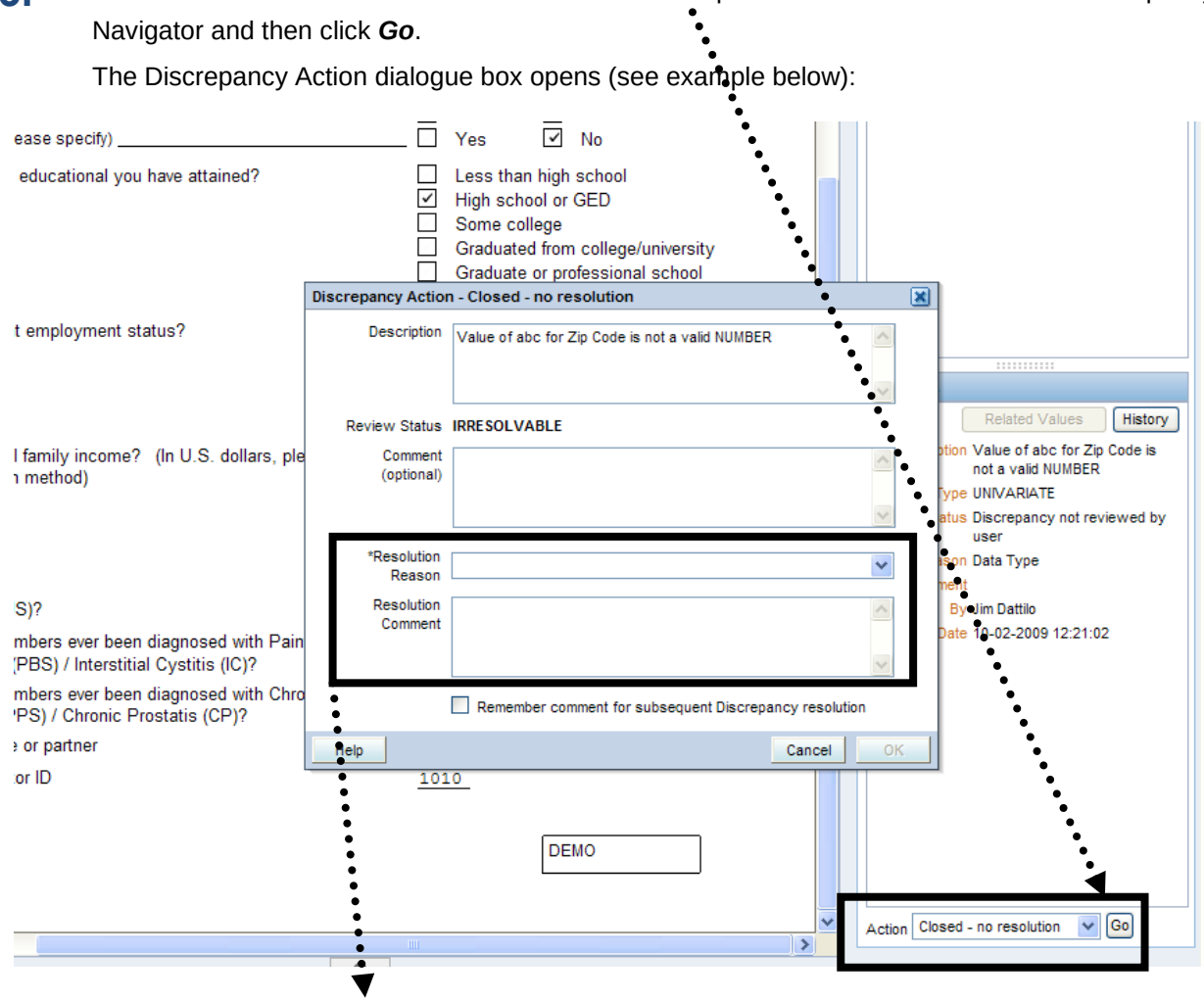
In some instance, data that triggered a discrepancy may be valid and you can document this within the Navigator Pane.

1. Click a CRF icon to open it in the DEW.

2. Open the Discrepancy Navigator and select the specific discrepancy.

3. Select ***"Closed – no resolution"*** from the **Action** dropdown list at the bottom of the Discrepancy Navigator and then click ***Go***.

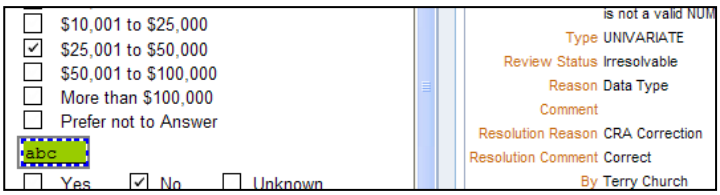
The Discrepancy Action dialogue box opens (see example below):



4. Supply a *Resolution Reason* and add a *Resolution Comment*

5. Click **OK**.

The field highlight will switch from red to green, and the Navigator Pane will display the Review Status as Irresolvable.



6. Save the CRF for the changes to take effect.

Using Highlights to Review Discrepancies

RDC Onsite highlights information in a CRF in different ways. To review a CRF using this feature:

1. Select the type of information to highlight from the **Highlight** dropdown selection list in the DEW toolbar.

ORACLE RDC Onsite: Data Entry
Study:TRANS_MAPP_EP, Site: 114315, Patient: 100002, Casebook: TRANS_MAPP_EP- (Terry Church - Data management role)
Highlight
All Discrepancies
Page 1/3

Options are:

- None,
- Active Discrepancies,
- Active and Other Discrepancies,
- Closed Discrepancies,
- All Discrepancies,
- Investigator Comments,
- Audit History, etc.

RDC Onsite highlights the associated fields accordingly, facilitating a quick review of the CRF.

2. Navigate to the highlighted field.

3. If the field is red, modify the data.

4. Save the CRF.

If the new value is valid for a field, the associated discrepancy will automatically close.

List of Abbreviations

AE	Adverse Event
CC	Coordinating Center
CCEB	Center for Clinical Epidemiology and Biostatistics
CDM	Clinical Data Management
CMED	Concomitant Medication Log
CRCU	Clinical Research Computing Unit
CRF	Case Report Form
DEW	Data Entry Window
DM	Data Manager
DMS	Data Management System
FDA	Food and Drug Administration
ICH	International Conference on Harmonization
IE	Internet Explorer
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INV	Investigator
MedDRA	Medical Dictionary for Regulatory Activities
NIH	National Institutes of Health
OC	Oracle Clinical
OPA	Oracle Project Administration
OS	Operating System
PC	Personal Computer
PDF	Portable Document Format
PI	Principal Investigator
PID	Patient Identification Number
QA	Quality Assurance
QC	Quality Control
RC	Research Coordinator
RDC	Oracle Clinical Remote Data Capture
SAE	Serious Adverse Event
SOM	School of Medicine
UPENN	University of Pennsylvania

Glossary[1]

A – B

Active — A *discrepancy status* that indicates the relevant discrepancy is actionable by members of your *user group*.

audit trail history — The set of all audit records for a given datapoint.

audit trail record — A set of information that describes an instance of data update. Each audit record includes the following information:

- the current value of the datapoint
- the previous value of the datapoint
- the username that changed the datapoint
- the timestamp the data update occurred
- the change reason
- an optional comment

Blank — An *entry status* designation that is assigned to a CRF a user has defined as blank. A Blank CRF does not contain data, nor can data be collected while it is marked as blank.

C

Cancel — A user action that halts the current process or action and reverts to the state of the application that immediately preceded the process or action, without changing the status of the system or data.

cancel button — In a dialogue or pop-up window, a cancel button causes the application to dismiss the window, disregard changes made in the window, and revert to conditions that existed before the window opened.

Casebook — The set of CRFs that are used to collect data for a patient over the course of the study. Each *patient* is assigned to a particular case book.

case report form (CRF) — A paper or electronic record associated with a patient in a study. Its purpose is to facilitate accurate collection of clinical data. CRFs are accessed through the PDF data entry window.

change reason — A constituent of an *audit record*. A standardized entry that explains why a datapoint changed. The change reason can be supplied either automatically (system-provided) or manually (user-provided). A user-supplied change reason is required when patient data changes after the CRF reaches *entry complete* data entry status.

Clinical Research Computing Unit (CRCU) — The Clinical Research Computing Unit (CRCU) is a designated core research facility providing state-of-the-art scientific services related to clinical data management and research computing. The CRCU is staffed with project management, clinical data management, and research computing professionals who support the development and implementation of large-scale, multi-center clinical trials, collaborative clinical and patient-oriented research, and multi-institutional health services research projects for Penn Medicine, which encompasses the CCEB, the School of Medicine, and the University of Pennsylvania Health System (UPHS). The development and support activities of the CRCU involve application development, database administration, project management, clinical data management, research computing, and technology support services.

[1] Abridged version of the Glossary from the *RDC User Guide*.

closed A *discrepancy status* that indicates the relevant discrepancy is not actionable by any *user group*. The discrepancy has been resolved, either by a user or the system.

CRF header An area of a CRF which consists of information that identifies a given CRF and the data that it collects. The information pertains to the patient, visit, investigator, and site. Much of the information included in the header is displayed in Patient Workbook Report, which allows you to print a casebook for a specific patient.

In the data entry windows, certain fields in the CRF header are required, that is, you must record that information before the system allows you to save the CRF.

RDC Onsite will not save a CRF to the study database until all required CRF header and CRF section header fields are collected.

current A discrepancy stat that indicates action can be taken on the discrepancy – either by a user or by the system.

current study The data set that is active. The name of the current study is displayed in the title bar of the Main Application Window.

D

data entry mode A designation that describes the method that is used to enter data into a CRF and save it to the study database.

data entry status A designation that describes the current state of data entry for a CRF. There are four data entry statuses:

1. created
2. blank
3. entry started
4. entry complete

data field A location in the Question area of the Data Entry window in which you type a value that is the response to a CRF question.

data point A location in a form where a data value may be entered. In most cases, a data point corresponds to a field in the data entry window.

data update The process of changing a CRF that has been *created* and saved to the database by altering a *data point* and saving the new version of the CRF to the database.

discrepancy Data that falls outside of an expected range of values or is otherwise "flagged" during the edit check process.

discrepancy management A process that systematically addresses discrepancies generated within a study. Discrepancy management attempts to identify the cause and assess the implications of each discrepancy and determine an appropriate action for the discrepancy. Its goal is to satisfactorily resolve all discrepancies associated with each CRF.

discrepancy record An entry which is part of the study database that defines the pertinent aspects of a discrepancy, from its initial occurrence and through each action that is taken on it.

discrepancy status A designation that describes the current state of a CRF with regard to discrepancies. There are four discrepancy statuses:

1. none
2. closed
3. active
4. other

E – F

electronic data capture (EDC) — A method of data collection for studies that uses computers at investigator sites as a mechanism to submit patient data and information to a centralized study database. Remote Data Capture (RDC) is an electronic data capture application.

entry complete — An *entry status* that is assigned to a CRF in which all required fields have been entered, including CRF header fields and Question area response datapoints.

entry started — An *entry status* that is assigned to a CRF in which data entry has been initiated but is not complete. CRFs that are assigned this entry status, some required data fields are complete, while some are not; the document has been saved in an incomplete status.

entry status — Formal stages of data entry, delineated in RDC, that track the progression of a CRF from no data entered ("created") through entry complete.

filter — A *saved search* that is applied to the Activity List window to limit the scope of the Navigation page and / or the activities that are available in the Task pane. It allows you to generate a more discrete and focused *workset* that is still based on an activity.

focus — Where the cursor is currently active. Focus may change from window to window, as when the cursor moves from the Main Application window to the first data field in the Data Entry window when you click a CRF cell.

H – I

header field — A location in the CRF header in which you collect values that provide information about the CRF. All required header fields must be collected before the system permits a CRF to be saved to the study database.

indicator question — A question used with certain *question groups* that allows "branching" during data entry based on the response.

For example, in a Drug Allergy question group, an indicator question could be, "Are you allergic to any drugs?"

- If the response is "Yes", the remaining questions in the question group, such as "Drug Name" and "Type of Reaction", require responses
- If the response is "No", the rest of the question group is not collected.

L

list of values (LOV) — A set of possible values for a data field. The list of values can generally be displayed by either clicking the button associated with list of value fields, pressing the List button, or by pressing the F9 key.

M

manual discrepancy — A *discrepancy* that is generated by a user, rather than a *data point* value. A manual discrepancy may be associated with an entire CRF, a CRF header, or a specific response in the question area of a CRF.

MedDRA The *Medical Dictionary for Regulatory Activities* – is a pragmatic, medically valid taxonomy of medical terms with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. It allows for uniform coding and reporting of medical signs, symptoms, and body systems for Adverse Event (AE) reporting. It was developed by the International Conference on Harmonization (ICH) and is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH steering committee.

multivariate discrepancy A *discrepancy* that is dependent on two or more *data point* values, which can be within a single CRF or across multiple CRFs and / or visits. A multivariate discrepancy is generated when a CRF is saved, which causes the system to run the validation procedures that locate this type of discrepancy.

N – O

news item A message that is communicated by the study sponsor to some portion of its RDC Onsite application users. News items are displayed in the News window.

open A designation for a *discrepancy* that indicates it is either in the *active* or *other* discrepancy status; that is, it is actionable by a *user group*.

A designation for a CRF that indicates it contains at lease one *active* or *other* discrepancy.

P

parameter A component of a *criterion* that you use to define a specific property of the data you wish to comprise the *workset*. A parameter may be comprised of settings that represent a value or range of values that, when combined with any other parameters in the same criterion, define specific data.

patient A human participant in a study. In RDC Onsite about whom data is collected. Each patient in a study is assigned a unique patient number that is associated with a particular site. In addition, the patient number is also assigned to a particular case book.

patient data The data that is collected about a participant in a study. This includes demographic information and clinical results.

patient list The set of patients that contain at leas one CRF which satisfies the search criteria.

patient number A designation for a set of patient data that is unique across a give study. Patient numbers are assigned to a study as part of the design process. Alternative terms include – patient positions, enrollment number, allocation number, and randomization number.

The following rules apply to all patient numbers:

1. Each patient number must always be assigned to a site.
2. Each patient number may not be assigned to more than one site at a time.
3. The first character in the patient number string may be a non-zero numeric or an alphabetic character.
4. If the first character in the patient number sting is alphabetic, the second character must be a non-zero character.
5. Only the first character may be alphabetic.

pending changes Changes that are made to a CRF that have not yet been committed to the study database. The changes that may be pending are response value, investigator comments, or discrepancies. The *save* action commits pending changes to the database.

privilege The ability for a user to perform a certain task. Privileges are granted to users in the Administration study and site maintenance windows by administrators. In general, users within a *user group*, that is, those that are given the same *role*, are assigned the same set of privileges.

The specific sequence that is employed at any time is defined by the Progression to next CRF setting in the Preferences window. In PDF mode, the browse sequence is invoked when you use the Previous and Next buttons.

Q – R

query A term that is a synonym for *discrepancy*. A procedure that is run against a database with the goal of returning a subset of data that satisfies the query criteria.

resolution A type of *discrepancy action* that causes the status to change from *active* to *closed*.

resolution reason A parameter associated with a *discrepancy action* that provides a reason when a user closes a discrepancy.

response value The value that is assigned to a datapoint. This term usually refers to the fields in the Question area of a CRF.

response sequence The order in which the system expects data to proceed, from one field to the next. Also termed “Tab Order”, this is determined for each question during the CRF design of study setup. It is utilized when you use the Tab key to navigate from one field to another.

S – T

save An action that commits pending data changes to the study database. In PDF mode, all save actions are explicit, initiated by the user clicking the Save button or choosing to save pending changes through the save edits / exit window.

save complete A save action that causes RDC to assign the CRF to the entry complete data entry status.

save incomplete A save action that causes RDC to assign the CRF to the *entry started* data entry status.

site A clinical location that participates within a give study.

timepoint A significant even in the history of a CRF. Used as criterion when viewing the Audit Trail tab. Examples of timepoints include:

- creation date
- verification dates
- approval dates

timestamp A value assigned to a datapoint that provides a chronology for significant events during a study. Such events include: the date / time when a value was created, the date / time when a value was updated, etc.

U

univariate discrepancy — A *discrepancy* that is dependent on the value of a single *data point*. This type of discrepancy is usually when the value recorded for a response does not meet certain criteria that has been deemed acceptable by the PI, protocol, or study sponsor.

unplanned — A designation attributed to any even or CRF that was not part of the protocol schedule or which occurs at a time other than was originally specified in the protocol schedule.

unplanned CRF — A CRF collected at a visit at which it was not planned, that is, it is not part of the casebook.

unplanned visit — A clinical event which occurs that was not scheduled by the protocol.

update — A process or condition in which CRF data or information, which has previously been saved is changed. A *privilege* that allows a user to initiate data entry, update data, initiate discrepancies, and update discrepancies.

user role — A database role that is granted to a user or user group. There are five default user roles, however, any given study database may include some or all of these, and may include protocol-defined roles. RDC allows privileges to be assigned independently of user role assignment.

V

validation — An action that entails the initiation and processing of sponsor-defined procedures, in the case of multiple datapoints, or edit checks, in the case of a single datapoint, that analyze collected data and return a query, or discrepancy, for each datapoint that does not meet the criteria defined in the procedure. Such a data-generated discrepancy is also referred to as a *validation error*.

validation error — A condition associated with one or more datapoints that indicates the value does not meet the criteria defined in a question definition or validation procedure. It is equivalent to a data-generated *discrepancy*.

value — When used in the context of criteria and parameters, the choice that you assign to a parameter, which was chosen from a list of possible values.

visit — A clinical even, which generally denotes the occurrence of a meeting between a patient and clinical staff at a study site. In the course of a visit, data related to the study is collected, which at some point is recorded and saved to the study database.

In RDC Onsite, a visit consists of one or more CRFs. By default, the system displays Spreadsheet Visit view in the Casebook Page, which displays, for the current patient list, all of the CRFs collected for a single visit.